# COLORECTAL CANCER SCREENING: A COLLABORATION WITH PUBLIC HEALTH AND PRIMARY CARE TO INCREASE COLORECTAL CANCER SCREENING IN A

## RURAL NORTH DAKOTA COMMUNITY

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#### Title

### COLORECTAL CANCER SCREENING: A COLLABORATION WITH

### PUBLIC HEALTH AND PRIMARY CARE TO INCREASE

### COLORECTAL CANCER SCREENING IN A RURAL NORTH

### DAKOTA COMMUNITY

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#### ABSTRACT

Colorectal cancer (CRC) is the second leading cause of cancer related deaths in the nation (Centers for Disease Control and Prevention [CDC], 2017a). Recommendations are to screen adults, ages 50-75 years (United States Preventative Services Task Force [USPSTF], 2016). While 64.4% of the population, ages 50-75 years, in North Dakota (ND) are participating in colorectal cancer screening (CRCS), there is a nationwide challenge to increase CRCS to 80% (National Colorectal Cancer Roundtable [NCCR], 2017; North Dakota Comprehensive Cancer Control Program [NDCRC], 2017).

The North Dakota Colorectal Cancer Roundtable (NDCCRT) accepted the challenge and recommended four strategies to increase CRCS; this project focused on the implementing FluFIT (fecal immunochemical test) Clinics. The purpose was to increase public awareness through education at FluFIT sites and increase screening rates with possible FIT to participants meeting screening criteria during the 2017-2018 influenza seasons (NCCR, 2017).

Potential participants, ages 50-75 years, coming to FluFIT sites for influenza vaccination were provided informational brochures and asked to fill out a survey regarding knowledge and factors impacting CRCS decisions to increase public awareness and aide future planning for improved screening processes through the ND county Public Health Department. Public Health collaborated with a primary care clinic in town to each host the FluFIT sites. The staff involved from both entities included nurses and clerical staff present at FluFIT sites, and health care providers from the Primary Care Clinic to enter orders for FIT screenings and follow-up on results.

iii

There were a total of 31 participants. Only five of these participants met criteria for CRCS with FIT testing between all sites, though none were able to complete screening through the FluFIT sites. The number of distributed informational brochures totaled 347.

Despite limited participation, the project increased community awareness on CRCS. The results also provided the ND Public Health Department with information on CRCS knowledge and beliefs to impact further research and identify barriers, while also supporting current literature that indicates there are unscreened individuals in ND. This project can assist future projects to merge the gap of the unscreened CRC population, leading to optimal health outcomes.

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v

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#### DEDICATION

I dedicate this dissertation to the greatest gifts that God has given me, besides life itself, my family. Throughout the dissertation process, my family has been my cornerstone to lean on when times were tough and have been a constant encouragement to get through this time in my life. I would not be where I am today without the influence you have had on my life. My husband, Josh, I dedicate this to you, as you were always cheering me on along with editing multiple sections of my dissertation. You were always there to pick me up when I felt like falling. Your own battle with cancer, acute myeloid leukemia, was a driving force behind this dissertation. You are an inspiration and I commend you for all that you have been through. You are a survivor! We are a great team that can get through anything, and that's why I thank you for being my rock and shoulder to cry on. I look forward to our bright future ahead and many years together. I love you!

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vii

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"Be strong and courageous. Do not be afraid; do not be discouraged, for the Lord your God will be with you wherever you go."

Joshua 1:9

viii

ABSTRACT	iii
ACKNOWLEDGEMENTS	v
DEDICATION	vii
LIST OF TABLES	xiv
LIST OF FIGURES	xv
LIST OF APPENDIX FIGURES	xvi
CHAPTER 1. INTRODUCTION	1
Background and Significance	1
Problem Statement	5
Objectives and Project Description	6
CHAPTER TWO. LITERATURE REVIEW	7
Introduction	7
Pathophysiology of Colorectal Cancer	7
Stages of Colorectal Cancer	9
Signs and Symptoms of Colorectal Cancer	
Screening Methods for Colorectal Cancer	
Stool Testing	
Flexible Sigmoidoscopy	
Colonoscopy	
Computed Tomography (CT) Colonography	
PillCam™ Colon Capsule	
Comparing Colorectal Cancer Screening Rates	
Cost Analysis of Screening	
Colorectal Cancer Morbidity and Mortality Rates	

# TABLE OF CONTENTS

Contributing F	actors Associated with Colorectal Cancer	
Diet and Life	estyle	
Age		
Genetics		
Barriers to Col	orectal Cancer Screening	
Increasing Cole	orectal Cancer Screening and Awareness	
Theoretical Fra	amework	
The Health Pro	omotion Model (Revised)	
Individual C	haracteristics and Experiences	
Behavior-Sp	ecific Cognitions and Affect	
Behavioral C	Dutcomes	
The Iowa Mod Care	el Revised: Evidence-Based Practice to Promote Excellence in He	ealth 30
Triggers and	Opportunities	
Purpose		
Priority		
Team Forma	ıtion	
Assemble, A	ppraise, and Synthesize Body of Evidence	
Sufficient Ev	vidence	
Design and I	Pilot the Practice Change	
Adoption		
Integrate and	l Sustain the Practice Change	
Disseminate	Results	
CHAPTER THR	EE. PROJECT DESIGN	
Methodology		
Resources		

Protection of Human Subjects	
Timeline	
CHAPTER FOUR. EVALUATION	
Evaluation Methods	
Objective Two	
Objective Three	
CHAPTER FIVE. RESULTS AND DISSUSSION	
Objective One Results	
Objective Two Results	
Year One Implementation	
Year Two Implementation	
Objective Three Results	
Results Compared to Literature	
CHAPTER SIX. DISCUSSION AND RECOMMENDATIONS	
Interpretation of Results	
Objective One	
Year One Implementation	
Year Two Implementation	
Objective Two	60
Objective Three	66
Dissemination	66
Relation to Pender's Health Promotion Theory	67
Relation to the Iowa Model	68
Limitations and Future Recommendations	69
Implications for Advanced Practice Nursing	

Application to DNP Roles	73
Conclusion	74
REFERENCES	76
APPENDIX A. EXECUTIVE SUMMARY	83
Project Summary	83
Background	83
Process	83
Findings and Conclusions	84
Recommendations for Further Action	86
APPENDIX B. HEALTH PROMOTION MODEL (REVISED)	87
APPENDIX C. PERMISSION TO USE NOLA PENDER'S HEALTH PROMOTION MODEL	88
APPENDIX D. THE IOWA MODEL REVISED: EVIDENCE-BASED PRACTICE TO PROMOTE EXCELLENCE IN HEALTH CARE	89
APPENDIX E. COLORECTAL CANCER AWARENESS BROCHURE	90
APPENDIX F. PERMISSION TO USE EDUCATIONAL BROCHURE	102
APPENDIX H. COLORECTAL CANCER AWARENESS SURVEY	103
APPENDIX I. FLUFIT STAFF TRAINING INFORMATION AND PERMISSION TO USE	105
APPENDIX J. PERMISSION TO USE THE IOWA MODEL	109
APPENDIX K. POSTER FOR PUBLIC HEALTH CLINIC	110
APPENDIX L. ORAL INFORMED CONSENT SCRIPT	111
APPENDIX M. SURVEY COVER LETTER	112
APPENDIX N. FIT COVER LETTER	113
APPENDIX O. FORMAL DOCUMENTATION FROM CLINICAL SITES	114
APPENDIX P. IRB APPROVAL	115

APPENDIX Q. IRB CONTINUING REVIEW REPORT	116
APPENDIX R. IRB: PROTOCOL AMENDMENT REQUEST	122

# LIST OF TABLES

Tabl	<u>e</u>	Page
1.	Survey Results for Objective One	50
2.	Qualitative Data from Survey Results: Why or why not continue colorectal cancer?	52
3.	Results from the Unscreened Participants	53

# LIST OF FIGURES

<u>Figu</u>	<u>re</u>	Page
1.	Nola Pender's Health Promotion Model 1.Image retrieved from Pender et. al., (2015, p. 35).	

# LIST OF APPENDIX FIGURES

Figure		Page
A1.	Survey Results	85
A2.	Benefits and Barriers to CRCS	85
A3.	Start or Continue CRCS	86

#### **CHAPTER 1. INTRODUCTION**

#### **Background and Significance**

Colorectal cancer is the second leading cause of cancer related deaths in the United States, affecting both men and women (Centers for Disease Control and Prevention [CDC], 2017a). In 2014, approximately 139,992 people in the United States were diagnosed with colorectal cancer (CRC), with 51,651 of those people dying from the disease (CDC, 2017b). In 2017, an estimated 95,520 people in the United States were diagnosed with colon cancer and 39,910 people were diagnosed with rectal cancer, with an estimated 27,150 men and 23,110 women of those numbers dying from CRC (American Cancer Society [ACS], 2017b).

In North Dakota (ND), the incidence range for CRC is 42.3 to 49.4 per 100,000 people with a mortality range of 14.5 to 15.6 out of 100,000 people (CDC, 2017b). Approximately 64.4% of the population of North Dakota whose age is between 50-75 years old are currently participating in colorectal cancer screening (CRCS) (North Dakota Comprehensive Cancer Control Program [NDCRC], 2017). According to the NDCRC, 60% of the CRC deaths in ND would decrease if everybody between the ages of 50-75 years old had regular CRCS (NDCRC, 2017). In addition, CRC is preventable, detectable and treatable when found early (NDCRC, 2017). The National Colorectal Cancer Roundtable (NCCR) and the American Cancer Society (ACS) collaborated in 2014 to launch a nationwide challenge to increase CRCS to 80% (National Colorectal Cancer Roundtable [NCCR], 2017).

The United States Preventive Services Task Force (USPSTF) recommends CRCS for adults beginning at age 50 years and continuing until the age of 75. The USPSFT recommends screening tests for CRC, such as fecal occult blood testing, sigmoidoscopy, or colonoscopy. The USPSTF CRCS recommendation is a grade "A," which means there is available evidence that

includes reliable results from well-designed, well-conducted studies in representative Primary Care populations that assess the effects of preventive service on health outcomes (USPSTF, 2016). According to the CDC (2017), 1 in 3 adults between the ages of 50-75 years of age, or about 23 million people in America, are not getting screened.

There are 1,400 organizations including health clinics and hospitals, non-profit health organizations, cancer coalitions, and government health entities that have signed the pledge for the 80% challenge across America, and the numbers keep rising (NCCR, 2017). Organizations that sign the pledge for the 80% challenge are making a commitment to join the efforts in working towards eliminating health disparities by providing access to CRCS throughout their communities (NCCR, 2017). Once an organization signs the pledge, they are listed as partners with the NCCR and will receive online tools and resources to assist their efforts in increasing CRCS (NCCR, 2017).

Since the launch of this challenge from the NCCR and ACS in 2014, there have been significant gains in CRCS rates, such as the National Health Interview Survey increased from 59% in 2013 to 63% in 2015, which means nearly four million people were screened for CRC from 2014 to 2015 (NCCR, 2017). Data from the Health Resources and Services Administration (HRSA) about screening rates at federally qualified health centers (FQHC's) have increased two percentage points each year for the past three years and jumped nearly four points in 2015 to 38.3% for screening rates for CRC. North Dakota needed to screen 68,000 people in 2017 to achieve the NCCR 80% (NCCR, 2017).

The ACS and the CDC conducted a market research sample and qualitative interviews with select audiences nationwide in 2014 (NCCR, 2017). The representative sample consisted of 1,023 U.S. adults 50 years of age or older and focused on the demographic and psychographic

data to assess which audiences were best to micro-target for CRCS (NCCR, 2017). Researchers from the ACS and CDC have identified major barriers to screenings surrounding people's perceptions, decreased knowledge about screening procedures, and lack of exposure to close relations with a cancer diagnosis that can be improved with education, particularly from a healthcare professional.

The North Dakota Colorectal Cancer Roundtable (NDCCRT), which is co-lead by the ACS and the North Dakota Department of Health (NDDOH), accepted the challenge from the NCCR of 80% of the population being screened for colorectal cancer which ended December 21<sup>st</sup>, 2018 (NDCRC, 2017). The NDCCRT is dedicated to reducing the incident rate and mortality rate of colorectal cancer throughout ND by using strategic planning and collaborative leadership. The NDCCRT provides four strategies that each have a workgroup actively involved to implement the strategy. The strategies that were utilized for this project included the first and fourth strategies. The first strategy and workgroup were FluFIT (fecal immunochemical test) clinics where CRCS and education was provided during influenza clinics. Increasing access to care at worksites was the second strategy and workgroup. Increasing provider's knowledge on CRCS was the third strategy and workgroup. The fourth strategy and workgroup were public awareness (NDCRC, 2017).

The FluFOBT (fecal occult blood testing) program was developed in 2004 by Dr. Michael Potter, a family physician and researcher at University of California, San Francisco (UCSF) and Dr. Larry Dickey, Medical Director in the Office of Health Information Technology of the California Department of Health Services (Department of Family and Community Medicine University of California, San Francisco [UCSF], 2016). Dr. Potter and Dr. Dickey thought that primary care visits that also included influenza vaccinations could be an ideal

opportunity to educate and screen eligible individuals for CRC, as health care providers are great messengers for health information (Agency for Healthcare Research and Quality [AHRQ], 2014). The first program was implemented in San Francisco, CA at the Chinatown Public Health Center that primarily serves a patient population that speaks Cantonese (AHRQ, 2014). Dr. Potter and Dr. Dickey thought that nurses would be great educators and assets in screening and handing out FOBT to eligible patients who presented for a primary care visit and who would like an influenza vaccination (AHRQ, 2014). For patient eligibility, they must have been between the ages of 50-80 years old and have not had a FOBT in the past year, flexible sigmoidoscopy in the past five years, or colonoscopy within the past ten years (AHRQ, 2014). Once the nurse determined if the patient was eligible, the patient was asked if he or she would like to learn more about CRC by watching an educational video in the Cantonese language, and then after the video, would offer a FOBT kit if the patient agreed to CRCS (AHRQ, 2014).

During the influenza season in 2004, 970 eligible patients received a FOBT during their primary care visit and flu vaccination, with 18% of the patients who completed the CRCS compared 1.7% of the 529 eligible patients who had primary care visits and did not receive the influenza vaccination during this time (AHRQ, 2014). In 2011, the San Francisco's Public Health Department switched to the FIT kits instead of guaiac FOBT kits as the FITs only require one stool sample compared to three for the guaiac FOBT kits and the FITs are more accurate at detecting CRC in the stool (AHRQ, 2014). Since the first study was completed in 2004, multiple FluFOBT or FluFIT's have been utilized to increase colorectal screening rates across the country (UCSF, 2016).

The NDCCRT is encouraging health clinics across ND to sign their pledge to help obtain 80% (NDCRC, 2017). Many different organizations throughout North Dakota have signed the

pledge with the NDCRC to help obtain this challenge goal. So far, 22 organizations across ND, including the rural community where this project took place, have signed the pledge. The rural town in ND has a population of approximately 16,000 people (Data USA, 2017). Prior to the project, the community had not implemented any of the four strategical projects that NDCCRT has recommended. Implementing a strategical plan in the town could help ND meet the CRCS goal of 80%. Colorectal cancer screening, education, and public awareness took place at influenza clinics throughout the community.

#### **Problem Statement**

Colorectal cancer's statistics of high death rate and non-gender biased affects, along with ease of prevention, detection, and treatment options, make targeting the strategies set forth by the NDCCRT worth encouraging (CDC, 2017a). The rural ND town was targeted due to the coinvestigator's association within the community, along with the presence of a large health organization and public health organization. The purpose of this practice improvement project was to increase public participation and awareness of colorectal cancer screening in a rural ND town. Working together with Public Health and Primary Care within a large health organization ensured the recommended key messengers delivered meaningful information to the potential unscreened population and merge the gap between the barriers of education and screening rates. Nurse Practitioners are healthcare providers and considered key assets in health promotion and prevention. Involving Nurse Practitioners and other healthcare professionals within the public health and primary care settings was intended to better help provide optimal health and wellbeing for the entire community during the practice improvement project.

#### **Objectives and Project Description**

The purpose of this practice improvement project was to increase public participation and awareness of colorectal screening specifically in a rural ND town. The co-investigator identified key people from both the Public Health Clinic and Primary Care Clinic to form a collaborative approach to assist the project and reach a broader population to better contribute to increasing CRC knowledge and screening rates in North Dakota. The administrator at the rural town's Public Health Clinic, who was referred to as the Public Health Liaison, offered her assistance in the project to implement a strategy from the NDCCRT, which included offering a FIT at influenza clinics to adults, ages 50 to 75 years. Objectives for the project include

- Increase the number of individuals receiving information on CRC and screening options for those ages 50-75 years of age by distributing informational brochures when present for influenza vaccination at the Public Health Clinic or the Primary Health Clinic during the 2017 and 2018 influenza seasons.
- 2) Identify barriers to screening within the rural ND town's population by developing and implementing a survey for those ages 50-75 years of age present for the influenza vaccination at the Public Health or Primary Care Clinic during the 2017 and 2018 influenza seasons to aide future planning for improved screening processes through the Public Health Department.
- 3) Positively impact screening rates for colorectal cancer in North Dakota by supplying 100 donated FIT's and distributing these during the influenza vaccination at a Primary Care Clinic and at a Public Health Department to individuals ages 50-75 years of age who have not yet had CRCS such as a FOBT or FIT within the last year or a colonoscopy within the last 10 years during the 2017 and 2018 influenza seasons.

#### **CHAPTER TWO. LITERATURE REVIEW**

#### Introduction

Colorectal cancer contributes significantly to cancer related deaths, yet is highly detectable, treatable, and preventable if caught in the early states (CDC, 2017a). According to the American Cancer Society (ACS), approximately 400 North Dakotans are diagnosed with CRC on an annual basis with 140 of them dying from the disease. There is a 90% five-year survival rate, with only 39% of these cases found at an early stage that could be attributed to low screening rates (American Cancer Society [ACS], 2017b).

A literature review was conducted to understand the pathophysiology of colorectal cancer, recommended screening methods, colorectal morbidity and mortality rates, contributing factors and possible barriers to CRCS, and methods to increase colorectal screening. A search through databases were conducted on CINAHL, PubMed, Medline, and the Cochrane Database of Systematic Reviews. Key words that were used were "colorectal cancer," "screening for colorectal cancer," "screening for colorectal cancer," "cost of screening for colorectal cancer," "barriers to screening for colorectal cancer," and "how to increase CRCS." The results yielded 1,381 randomized controlled trials found on PubMed; 15 systematic reviews from the Cochrane database along with 1,473 controlled trials; CINAHL yielded 995 academic journal articles and 14 dissertations; Medline yielded 7,518 academic journal articles and 65 guidelines for CRCS.

#### **Pathophysiology of Colorectal Cancer**

Colorectal cancer occurs in the colon or the rectum. Every six weeks the mucosa in the large intestine regenerates (Cagir & Espat, 2017). Colorectal cancer occurs when crypt cells, in the intestines, migrate from the crypt to the surface of the intestinal wall where they undergo changes and lose the ability to replicate, such as differentiation and maturation. Since the crypt

cells can no longer mature or differentiate, a polyp can develop. A polyp is a protrusion into the lumen of the gastrointestinal tract. Colorectal polyps can be benign (adenoma) or cancerous (adenocarcinoma) (Cagir & Espat, 2017). Polyps can take on different shapes and either be a raised protuberance with a broad base, known as a sessile polyp, or a pedunculated polyp where it is attached to the bowel wall by a stalk that is narrower than the body (Grady & Markowitz, 2014). Many factors play a direct role on influencing how fast the polyp grows, including gene mutations, epigenetic alteration, and local inflammatory changes (Grady & Markowitz, 2014).

Most colorectal carcinomas are adenocarcinomas. Other forms of colorectal carcinomas that are not as common include lymphomas, gastrointestinal stromal tumors, leiomyosarcomas, carcinoid tumors, and melanomas (Cancer Treatment Centers of America, 2017). There are three pathways that colorectal carcinoma has been described: adenomatous polyposis coli (APC) gene adenoma-carcinoma pathway; hereditary nonpolyposis colorectal cancer (HNPCC) pathway; and ulcerative colitis dysplasia (Cagir & Espat, 2017). The APC gene adenoma-carcinoma pathway occurs when several genetic mutations take place causing inactivation of the APC gene, activation of the K-ras oncogene and p53 mutations leading to a loss in tumor suppressor gene function that prevents cellular death or apoptosis prolonging the cell's lifecycle. When the APC mutation is inherited, the mutation causes a familial adenomatous polyposis syndrome. The second pathway occurs when there are mutations in the mismatch repair genes within the DNA. A mismatch in the DNA's repair genes occurs in 90% of people with hereditary nonpolyposis CRC (HNPCC). Adenomas are more common than adenocarcinomas and have a 10% chance of turning into adenocarcinoma within the next 10 years after diagnosis (Cagir & Espat, 2017).

#### **Stages of Colorectal Cancer**

There are four stages of colorectal cancer that typically start out as a polyp leading to cancer In Situ where the cancer has formed and is not growing into the colon or rectum wall (CDC, 2017a). Stage one occurs when the cancer has gown through the superficial mucosa of the colon or rectum and hasn't spread to any other locations (ACS, 2017a). Stage two occurs when the cancer has advanced through the wall of the colon or rectum and hasn't spread to any nearby lymph nodes. Stage three occurs when the cancer grows beyond the wall colon and rectum affecting nearby lymph nodes. Stage four is when the cancer has metastasized to distant sites throughout the body including other organs, such as liver or lungs (ACS, 2017a). Along with the stages of colorectal cancer, the American Joint Committee on Cancer (AJCC) developed a classification and staging for colon cancer based on tumor/node/metastasis (TNM) (Cagir & Espat, 2017). The TNM classification and staging helps guide the treatment plan for anyone affected by colorectal cancer.

Identifying risk factors can help determine which screening test is appropriate for individuals. Average risk individuals include people who have no identifiable risk factors, such as have never had CRC before, a relative who had colorectal cancer, or any have symptoms of colorectal cancer (McKenzie, Talukder, & Albo, 2017). The recommendation for average risk individuals is to have the stool testing done every 1-3 years depending on which test in completed. High risk individuals include people who have had colorectal cancer, family history of colorectal cancer, are African American, have a history of polyps or inflammatory bowel disease (IBD). Inherited syndromes also put an individual at a high risk for colorectal cancer. These disorders include HNPCC, familial adenomatous polyposis (FAP), and/or Peutz-Jeghers syndrome (McKenzie et al., 2017).

The American Gastroenterology Society recommends beginning colorectal screening at age 45 for African Americans, as this population has the highest CRC incidence and mortality rate in the United States. The reason that African Americans experience the highest mortality and morbidity is not clear and could be from either biological reasons or lower rates of screening (McKenzie et al., 2017). An individual with a family history should get screened at least by age 40 or 10 years before the age that their relative was diagnosed with CRC (ACS, 2017a). Individuals with IBD should undergo regular testing including colonoscopies to detect any changes in intestinal wall, along with biopsies as needed starting at 8 to 10 years after onset of symptoms, followed by screening every 1 to 2 years (ACS, 2017a). Genetic testing is available and recommended for individuals with a familial history of colorectal cancer (McKenzie et al., 2017). Individuals with a family history of HNPCC should start screening with a colonoscopy at the age of 25 as there is a 52-69% chance of developing CRC in their lifetime. Individuals suspected of having FAP should undergo flexible sigmoidoscopy for a definite diagnosis at the age of 10 or 12 years of age. As these individuals develop hundreds to thousands of polyps in colon or rectum, a colectomy is recommended if tested positive for the gene (McKenzie et al., 2017).

#### Signs and Symptoms of Colorectal Cancer

Symptoms of CRC can often go unnoticed, especially in the early stages. The symptoms include, and are not limited to, blood in stool, abdominal pain, decrease in appetite, and weight changes (ACS, 2017a). The most common symptom is bleeding, which occurs in approximately 60% of patients diagnosed with CRC (Cagir & Espat, 2017). Bleeding can also be attributed to other causes, such as hemorrhoids. A change in bowel patterns occur in 43% of patients, and 26% of all patients test positive for occult bleeding using a fecal occult blood test (FOBT).

Abdominal pain is present in about 20% of patients, usually attributed to a bowel obstruction. Overall weakness or fatigue occurs in 9% of patients with CRC. Back pain, pelvic pain and urinary symptoms are late signs of the progression of CRC occurring in 5% of patients at the time of diagnosis (Cagir & Espat, 2017). A sign of CRC is microcytic anemia, and when found in men of any age and women who are postmenopausal, indicate CRC until proven otherwise, preferably with a colonoscopy for definite diagnosis (McKenzie et al., 2017). Another sign is a palpable abdominal mass found with a physical exam, which is often a late sign of the disease progression. Signs of anemia, such as pallor skin and mucous membranes, may be present on physical examination (McKenzie et al., 2017).

The signs and symptoms of CRC can be vague and some patients may exhibit different symptoms than others. Providing preventative screening on a regular basis is very important since the symptoms usually do not present themselves until the late stages of CRC (ACS, 2017a). Screening is imperative to prevent, detect, and start treatment early to decrease the morbidity and mortality rate associate with the disease (ACS, 2017a).

#### **Screening Methods for Colorectal Cancer**

Screening methods for CRC can help detect cancers early that can ultimately help decrease the mortality rate associated with CRC (ACS, 2017a). There are a variety of different screening tests available for CRC that vary in the degree of invasiveness. Each testing method has specific guidelines on testing and how often to perform each test.

#### **Stool Testing**

Stool testing offers a non-invasive way to detect CRC adults ages 50 to 75 years of age who have an average risk for CRC and who are without symptoms of colorectal cancer. There are three different tests that involve stool testing that can be performed at home and then returned

to their health care provider for testing. The first stool test is the guaiac-based fecal occult blood test (gFOBT) that uses the chemical guaiac to detect any blood in the stool. There are no diet changes, time off from work, or bowel prep that is required for this test (USPSTF, 2016). A bowel prep involves such things like ingesting laxatives, enemas, or suppositories to help evacuate stool from the bowels (American Society for Gastrointestinal Endoscopy, 2017). A stool sample is required and then is used to insert a brush or stick and then smeared onto a card provided (CDC, 2017a). After smearing the stool onto the card, the remaining stool is no longer needed and can be discarded. Random controlled trials revealed that newer versions of the gFOBT have a high sensitivity rate compared to older versions (USPSTF, 2016). The sensitivity rate ranges from 62%-79% and a specificity of 87% to 96% for detecting CRC (USPSTF, 2016). The sensitivity of the test determines how accurate the test is at detecting CRC (a true positive) and the specificity shows how accurate the test is at not detecting CRC (a true negative) (Gogtay & Thatte, 2017). Medicare covers an initial preventative physical exam which covers this test completely at no cost during the first year of enrollment (ACS, 2017a). Medicare Part B covers yearly wellness visits after 12 months of enrollment at no cost (ACS, 2017a). Blood in the stool may mean that there are some changes going on in the colorectal area that did need to be followed up with further testing, such as a colonoscopy, as this test only detects blood and not polyps (CDC, 2017a). The ACS (2017a), recommends having this test done annually.

The next stool test is a fecal immunochemical test (FIT) that uses antibodies to detect blood and cancer in the stool and does not identify any polyps (CDC, 2017a). The FIT testing is a non-invasive at home test for CRC that doesn't require a bowel prep, diet changes, or time off from work (CDC, 2017a). The stool sample is obtained in almost the same manner as the guaiac test, however, this involves a small tube with an applicator. After having a bowel movement, the

patient unscrews the applicator that has a spiral brush attached to it and pokes the sample in six different sites on the stool sample before returning the applicator to the tube (NCCR, 2017). The stool sample is no longer needed and be discarded after completing the six pokes. A FIT is recommended for average-risk patients, screening is annually, and positive tests must follow up by a colonoscopy (NCCR, 2017). The FIT is more sensitive and specific than the gFOBT at detecting cancer cells (USPSTF, 2016). The sensitivity range is between 73%-75% and a specificity of 75% to 95% to detect CRC (USPSTF, 2016). The cost of FIT testing is fairly inexpensive, and Medicare covers this test at no cost (ACS, 2017a).

The FIT-DNA (Cologuard) is the last stool test that is available for colorectal testing. The FIT DNA test combines the FIT with a test that detects altered DNA in the stool (CDC, 2017a). The FIT test requires the entire stool sample to be sent to the lab for testing. No cards or poking the stool are required, only the stool sample itself. The Cologuard test can be done in the privacy of your home and does not require a bowel prep, diet changes, or time off from work (Exact Sciences, 2017). The FIT-DNA test is recommended to be completed every three years. Positive results are recommended to be followed up with a colonoscopy. Medicare covers this test at no cost beginning at age 65 to 85 years of age with a low risk and no symptoms of CRC (ACS, 2017a). The sensitivity rate is 92% and the specificity rate of 84% for the FIT-DNA test at detecting CRC (USPSTF, 2016). The sensitivity for the FIT-DNA test to detect precancerous lesions is 42% with a specificity rate of 87% (USPSTF, 2016). A study was done to compare the FIT with the FIT-DNA and found that the FIT-DNA detected more cancer cells than the FIT, however the incidence of false positives was higher along with an increase in insufficient stool samples (Imperiale, Ransohoff, Itzkowitz, Levin, & Lavin, 2014).

#### Flexible Sigmoidoscopy

A flexible sigmoidoscopy (FS) is an invasive test that is performed by a qualified health care provider. The flexible sigmoidoscopy is a thin, short, flexible scope that is inserted through the anus and into the lower third of the colon to check for polyps or cancer used as a screening tool or diagnostic measures (CDC, 2017a). An FS is recommended every five years with a FIT annually (NCCR, 2017). Before the test occurs, a bowel prep is required to visualize the lining of the sigmoid colon and rectum (ACS, 2017a). During the test some sedation is used to provide comfort and relaxation as this test can cause some cramping and urge to have a bowel movement. Transportation home after the test is required due to the sedation that was used during the test (ACS, 2017a).

Medicare covers this test beginning at age 65 or older (no co-insurance, co-pay or Part B deductible) when testing is done for screening only. In some cases, this screening method begins as a screening tool and turns into a diagnostic measure. If the health care provider performing the test identifies any polyps or cancerous lesions that require removal and biopsy, the individual will be charged co-insurance or co-pay for the diagnostic testing. If a precancerous polyp or CRC is found, a colonoscopy would be required to visualize the entire colon to detect other polyps or cancer (ACS, 2017a). The USPSTF (2016) found the benefit of this testing is less beneficial when done alone compared to when the FS is combined with an annual FIT. The availability of flexible sigmoidoscopies has declined in the United States (USPSTF, 2016).

#### Colonoscopy

The colonoscopy is like the flexible sigmoidoscopy; however, the colonoscopy is inserted through the entire colon whereas the sigmoidoscopy only goes to the sigmoid colon. A colonoscopy is recommended every 10 years for those who are at average risk and every two

years for those at high risk, such as individuals with IBD or HNPCC (ACS, 2017a). Before the test occurs, a bowel prep at home is done in order visualize the lining of the colon during the test. Specific instructions regarding medications, bowel prep, and eating the night before the test is determined by the health care provider (ACS, 2017a). During this test, health care providers can find and remove polyps and some cancers (CDC, 2017a). Sedation is usually given to help the body relax and decrease the feeling of cramping and pressure throughout the lower abdomen (ACS, 2017a). Transportation home is required due to the sedation that was used during the test. Colonoscopy results are highly specific at finding cancer, however, colonoscopies can miss some small polyps (ACS, 2017a). Screening and diagnostic measures can be performed during the same examination (USPSTF, 2017). The same as Medicare stipulations that apply for the FS apply for a colonoscopy as well (ACS, 2017a).

#### **Computed Tomography (CT) Colonography**

A CT colonography, also called a virtual colonoscopy, takes images of the entire colon for health care providers to analyze for any signs of polyps or cancer (CDC, 2017a). This testing often involves a double contrast barium enema prior to the imaging. A full bowel prep is required before testing to view the lining of colon and no sedation is used during the test (ACS, 2017a). The ACS recommends having this done every two years for those who are 50 years or older at higher risk and every four years for those who are 50 years or older at average risk. If polyps or cancer is found further action is required, such as a colonoscopy or surgical procedure to remove the lesion or polyp. Currently Medicare does not cover this test (ACS, 2017a).

#### **PillCam™** Colon Capsule

The PillCam<sup>™</sup> Colon Capsule is a new way to detect CRC. The first PillCam Colon capsule was released in 2006 followed by the PillCAm Colon 2 capsule that was released in 2012

(De Vincentis et al., 2012). The PillCam 2 is more sensitive at finding polyps compared to the first version. The PillCam is a disposable camera that is inserted into a pill-like capsule that takes pictures of the entire colon once orally ingested with a 10-hour battery life. The bowel preparation is the same as the preparation is for the colonoscopy. The PillCam Colon 2 has a sensitivity rate of 89% for > 6mm polyps and 88% for >10mm polyps (De Vincentis et al., 2012). Currently, the U.S. Food and Drug Administration (FDA) only approves the PillCam to be used for individuals at average risk for CRC who undergo an incomplete colonoscopy that requires further evaluation; for patients who cannot undergo a colonoscopy; have adverse reactions to sedation or have lower gastrointestinal (GI) bleeding (Darrow, J. 2014).

#### **Comparing Colorectal Cancer Screening Rates**

The USPSTF (2016) has not found sufficient evidence that identifies any one of these CRCS tests as the best in detecting colorectal cancer, however there have been studies done on the level of evidence supporting the test along with strengths and limitations. Random control studies identified that gFOBT testing has a higher sensitivity than older versions, however, this test has a high false positive rate. The FIT has improved sensitivity over the gFOBT testing, however, the FIT can produce false-positive results as well. The FIT-DNA (Cologuard) test has a higher sensitivity, but a lower specificity than the FIT which results in a higher false positive result leading to more invasive procedures that may not be necessary. Colonoscopy is highly specific and sensitive at detecting colorectal cancer, however colonoscopies can miss small polyps (USPSTF, 2016). There have not been any studies done that compare the test characteristics between a colonoscopy and a flexible sigmoidoscopy. Studies of CT colonography have not focused on the ability to detect cancer, rather they focus on finding adenomas with or without a bowel prep. A CT colonography has a sensitivity rate of 67% to 94%

and a specificity of 86% to 98% with a bowel preparation and without a bowel preparation the CT colonography has a sensitivity range of 67% to 90% and a specificity of 85% to 97% at detecting adenomas (USPSTF, 2017). Discussing options along with risk factors with a primary care provider is best to help make the decision of which testing is right for everyone (Cagir & Espat, 2017). The research appears to be beneficial at starting out with a FIT test for people who have never been screened for CRC and are at average risk.

#### **Cost Analysis of Screening**

Looking at the cost of each test along with the insurance of everyone is important. Many private insurances cover the cost of preventative colorectal screening, however, they may charge for diagnostic services along with bowel prep, pathology costs, anesthesia, and facility fees (ACS, 2017a). Medicaid coverage varies state to state for coverage of colorectal screening (ACS, 2017a). The average cost for a FOBT and FIT without insurance ranged from \$48 to \$149 across America, including the cost for screening and diagnosis (Tangka et al., 2013). The average cost of FIT-DNA (Cologuard) as of March 2017 is \$648 (Exact Sciences, 2017). The average cost of a colonoscopy ranged from \$654 to \$1600 across America (Tangka et al., 2013). The average cost for a PillCam is \$500 (Darrow, 2014).

Wong, Ching, Chan, and Sung (2015) conducted a cost-analysis of colorectal screening and found that implementing tailored programs based on age and gender could be more costeffective. The cost-effectiveness analysis found that having a colonoscopy every 10 years starting at age 50 in both men and women was more cost-effective than having a flexible sigmoidoscopy (FS) every 5 years. The analysis did show the most cost-effective method between genders was to have females receive a FS every five years until age 60 and then receive a colonoscopy at age 70, while screening all men with colonoscopies, starting at age 50, was the

most cost-effective method. The most cost-effective colorectal stool screening was found to be the FIT from their cost-effectiveness analysis (Wong, Ching, Chan, & Sung, 2015).

Screening for gFOBT was found to be less sensitive with a higher false positive rate than the FIT, which is more sensitive and specific towards analyzing hemoglobin found in feces (Allison, Fraser, Halloran, & Young, 2014). They also concluded that FIT was less messy and easier to complete than the gFOBT (Allison et al., 2014).

The CDC (2017) has estimated that America spent \$14 billion in CRC medical costs in 2010. Medical costs associated with CRC would decrease by screening more people and detecting CRC at an early stage (CDC, 2017a). Using the FIT for average risk populations appears to be best at detecting cancer, as the FIT is more specific and easier to collect a sample than the gFOBT stool test, supporting FIT a good choice to utilize during influenza vaccinations.

#### **Colorectal Cancer Morbidity and Mortality Rates**

Colorectal cancer is the third most common cancer and the second leading cause of cancer related deaths in America (ACS, 2017b). The ACS predicts that America saw 95,520 new cases of colon cancer and 39,910 new cases of rectal cancer along with 50,260 deaths in 2017. The risk of developing CRC in a lifetime is about 1 in 21 (4.7%) men and 1 in 23 (4.4%) women (ACS, 2017b).

The ACS (2017a) attributes the dropping death rate for CRC in recent years due to the increase in screening, earlier diagnosis, and immediate treatment initiation. There are more than one million CRC survivors due to completing colorectal screening (ACS, 2017a). Increasing the awareness of colorectal screening in ND could help drop the death rate even further.

#### **Contributing Factors Associated with Colorectal Cancer**

Contributing factors associated with CRC include diet, age, and genetics. Understanding how each of these contributing factors is associated with colorectal could help empower people to lower their risk of CRC by changing their diet, knowing at what ages their risk is increased, and seeking CRCS earlier based on their genetic and health history (NCCR, 2017). Modifiable risk factors consist of things a person can change, including diet and lifestyle changes, whereas non-modifiable risk factors consist of things that a person cannot change, such as age and genetics (ACS, 2017a).

#### **Diet and Lifestyle**

A diet high in fat, low in fiber, and low in fruits and vegetables can increase the risk of CRC, along with being overweight or obese (NCCR, 2017). The ACS (2017a) recommends maintaining a body mass index (BMI) ranging from 18-25. Avoiding tobacco products, limiting alcohol intake, increasing physical activity, and limiting screen time and other sedentary activities are also recommended to decrease the risk of CRC (ACS, 2017a). Stress, depression, and anxiety can lead to developing unhealthy habits, such as increasing alcohol or tobacco intake, eating foods high in fat and low and fiber, and decreasing physical activity (Lee et al., 2015). All of these are risk factors for CRC, however there have not been any studies to prove that there is a direct link between physiological stress, depression, and/or anxiety with CRC (Lee et al., 2015).

#### Age

The USPSTF found significant evidence that the population most at risk for developing CRC is between the ages of 50-75 years, thus recommending starting colorectal at the age of 50 years (USPSTF, 2015). The conclusion to screen for CRC beyond 75 years of age should be an

individual decision that would be most appropriate for people who are healthy enough to undergo treatment for CRC if detected and do not have chronic health conditions that would affect or limit life expectancy (USPSTF, 2015). Working together with a primary care provider would be appropriate for people to make an informed decision regarding the risk and benefits of CRCS beyond 75 years of age.

#### Genetics

The risk of CRC is higher with a blood relative that has had polyps or colorectal cancer. Inflammatory bowel disease, Chron's disease, or ulcerative colitis also increases the chance of developing colorectal cancer (NCCR, 2017). Genetic syndromes can also predispose a person for the risk of developing colorectal cancer, such as familiar adenomatous polyposis (FAP) or hereditary nonpolyposis colorectal cancer (NCCR, 2017).

#### **Barriers to Colorectal Cancer Screening**

Barriers to colorectal screening need to be addressed to prevent, detect, and treat CRC early. Understanding the barriers of CRCS has been beneficial to better merge the gap between the screened and unscreened population. The most significant barriers addressed by the NCCRT (2017) included a rationalized avoidance, lack of affordability, no symptoms or family history, negative connotation, no provider recommendation, no personal connection, and decreased healthy habits. The CDC (2017a) recognized three reasons why people do not get screened, including a health care provider didn't tell them to get screened, they didn't realize that everyone's risk increases with age, that they didn't have health insurance or a health care provider, and that they feared the test results would turn out positive for cancer. Certain populations have been identified for having lower CRCS rates, and can include Hispanics, uninsured people, and people who have Medicaid (NCCRT, 2017). People who are younger have
a lower rate of being screened for CRC; for example, approximately 18.3 million between the ages of 50-64 years are needing to be screened compared to 6.1 million between the ages of 65-75 years needing to be screened throughout the United States (NCCRT, 2017). Access to care, language barriers, low socioeconomic status, and sociocultural factors could all be some of the traits of the unscreened population (Gupta et al., 2014).

The researchers from the ACS and CDC found that the unscreened population are more likely to be younger, 50-59 years old, more likely to be uninsured, slightly lower income (<\$40,000/year), more likely to be Hispanic, less likely to have a four-year college degree, less likely to be a cancer survivor, or have a close relative or friend affected by CRC than those who have been screened (NCCR, 2017). The emotional profile of the study showed that people that are unscreened feel that they are taking good care of their health, are fearful of the unknown and of the procedure, are focused more on immediate health concerns, are procrastinators, are rationalizing reasons for not being screened, are lacking a sense of urgency around CRCS, and are tending to have an attitude of "I know what's best for me" (NCCR, 2017).

Breaking down barriers for CRCS is essential to reach unscreened populations. The ACS and the NCCRT Public Awareness task group developed six key messages to help motivate people to get screened for colorectal cancer. The six key messages included: support and testimony; empowerment and control; physical survivor/expectation; trust; options; and affordability (NCCRT, 2017). Incorporating the "right" messenger along with having the "right" message was equally important, so the NCCR addressed main messengers to target the unscreened population. The first key messengers were health care providers, as health care providers are a very trusted source of information. The second key messengers were the community and nonprofit organizations, as many of the unscreened population do not regularly

see their health care provider. Celebrities were the third messengers, as they can engage the unscreened population on a more emotional level. The fourth messengers were survivors, as they are more personal and provide a direct relationship to CRC. The last messengers addressed were insurance carriers that can help clear up the confusion with the cost of colorectal screening methods. The NCCR (2017) found that the messages that resonated the most with the unscreened population should specifically focus on addressing misperceptions and fears around testing, showcase testimonials of people who have had the screening done, and provide information to make an informed decision on which screening method is right for them (NCCR, 2017).

Psychological effects of colorectal screening could also be a barrier. For example, false positive results could lead to further CRC testing and procedures, such as an unnecessary colonoscopy, leading to financial and emotional burden. Kirkoon et al. (2016) conducted a randomized controlled trial that consisted of participants who were either invited to have FS screening or a FIT and then complete a questionnaire that consisted of an anxiety and depression scale. Participants completed the questionnaire when they were screened and again one year after screening. The researchers found that most participants did not show psychological effects from CRCS one year later, and only a few had anxiety related to FS screening (Krikoon et al., 2016).

#### **Increasing Colorectal Cancer Screening and Awareness**

Increasing awareness and screening for CRC can help save 203,000 by 2030 if 80% of America's population, who are 50-75 years of age, are screened for colorectal cancer (NCCRT, 2017). To meet this goal, 68,000 adults in North Dakota need to be screened for CRC (NDCCRT, 2017). The population of North Dakota is approximately 757,952 with a median age 35.4 year of age (United States Census Bureau, 2015). The rural ND town's population where the project took place, is approximately 15,400 people with a median age of 39.6 years (United

States Census Bureau, 2015). The median household income is \$51,217 per year with a poverty rate of 12.8% (Data USA, 2017). The predominant race and ethnicity in the rural ND town are Caucasians, making up 87.9%% of the population. Hispanics make up 3.6%; American Indians make up 5.5%; African or Black Americans make up 2.9%; Asian or Pacific Islander make up 1.5%. (United States Census Bureau, 2015)

Guillaume et al. (2017) conducted a cluster, randomized controlled trial in France that utilized screen navigators that consisted of social workers who reached out to people in the low socioeconomic class who were associated with low participation levels without a history of CRC regarding colorectal screening. The results appeared to be beneficial by increasing the number of people screened in France. Effective outreach strategies for targeting the unscreened population has been proven to be beneficial through multiple randomized controlled trials that include utilizing mailed invitations to complete gFOBT or FIT, telephone calls to promote awareness, and offering a gFOBT or FIT and education at the time of annual influenza vaccinations (Guillaume et al., 2017).

A multisite, randomized trial measured the effectiveness of a FluFIT program to show an increase across all sites in screening rates for people who have not had CRCS (Potter et al., 2013). Providing CRC education and screening during influenza vaccinations shows promising results to increase screening rates and target the unscreened population as many of the participants from this study saw their primary care provider 0-1 times within the past year (Potter et al., 2013). A randomized clinical trial compared the repeat annual CRCS rates for adults, ages 50 to 64 years, over a three-year period (Singal et al., 2017). The intervention group received a mailed invitation for either a FIT or colonoscopy based on their previous results and the control group received usual care at their annual physicals. The results showed that 38.4% of the

individuals who received the colonoscopy invitation completed the screening along with 28% of individuals who received the FIT invitation, and 10.7% of the individuals who received usual care completed the screening (Singal et al., 2017). The results support that mailing invitations for colorectal screening could be promising at increasing repeat annual colorectal screening. Weiner et al. (2017) conducted a pilot study to assess the feasibility of implementing office systems changes to support a universal CRCS in FQHC's and found that the results were higher for clinics when key informants or champion leaders were leading the practice change.

The FluFOBT (fecal occult blood testing) program was developed in 2004 by Dr. Michael Potter, a family physician and researcher at University of California, San Francisco (UCSF), and Dr. Larry Dickey, Medical Director in the Office of Health Information Technology of the California Department of Health Services (Department of Family and Community Medicine University of California, San Francisco [UCSF], 2016). Dr. Potter and Dr. Dickey thought that primary care visits that also included influenza vaccinations could be an ideal opportunity to educate and screen eligible individuals for CRC, as health care providers are great messengers for health information (Agency for Healthcare Research and Quality [AHRQ], 2014). The first program they implemented was in San Francisco, CA at the Chinatown Public Health Center that primarily serves a patient population that speaks Cantonese. Dr. Potter and Dr. Dickey thought that nurses would be great educators and assets in screening and handing out FOBT to eligible patients who presented for a Primary Care visit and who would like an influenza vaccination. For patient eligibility, they must have been between the ages of 50-80 years and have not had a FOBT in the past year, flexible sigmoidoscopy in the past five years, or colonoscopy within the past ten years (AHRQ, 2014). Once the nurse determined if the patient was eligible, the patient was asked if he or she would like to learn more about CRCS. If the

patient did, then an educational video that was four minutes in length in the Cantonese-language was offered. The nurse answered all the patient's questions after the video and then distributed a FOBT kit if the patient agreed to be screened. Along with the FOBT kit, a prepaid return envelope and one-page instruction sheet in the Cantonese language, along with the clinic's contact information in case the patient had any questions was provided. The nurse would then document the patient's response to the influenza vaccination and FOBT kit on a log sheet that would later be entered into the electronic health record (EHR) (AHRQ, 2014).

The FluFIT program was reviewed by the National Cancer Institute (NIH) and the Agency for Healthcare Research and Quality (AHRQ) with both organizations finding significant evidence that the FluFIT program is effective at increasing CCS rates (AHRQ, 2014; National Cancer Institute [NIH], 2017). The NIH reviewed two FluFOBT (fecal occult blood testing) studies and one FluFIT study that were all conducted in California. The NIH found in the first study that patients who were given a FOBT with their influenza vaccination increased the CRCS rates from 21.8% to 38% compared with 17.6% to 21.7% in the control group, which only received the influenza vaccination (p=.01). The second study the NIH reviewed found that 21.6% of the people who were given a FOBT during their influenza vaccination completed the testing compared with 11.8% who completed CRCS throughout the year who did not receive a FOBT during their influenza vaccination. The third study reviewed was a FluFIT study that showed within 90 days of receiving a FIT at the patient's influenza vaccination, 26.9% of patients completed the testing compared to the control of 11.7% who completed a FIT and only received the influenza vaccination (p<.0001 for both analyses) (NIH, 2017).

Verma, Sarfaty, Brooks, and Wender (2015) recommended using a population-based program for increasing CRCS in the United States, as they completed a literature review of all

population-based programs that were members of the NCCRT. Their review found that population-based approach that targeted a defined population, provided screening and treatment options, and monitored quality was shown to have a successful rise in CRCS rates (Verma et al., 2015). Organizations that utilized the International Agency for Research on Cancer (IRAC) cancer prevention framework to guide their program to increase CRCS rates were found more likely to have the most successful increase in screening rates. The IRAC criteria included: 1) screening policy with specified age categories, screening methods, and intervals; 2) a defined population; 3) management team responsible for implementation; 4) health care team to help make decisions; 5) quality assurance; and 6) a method identifying cancer occurrence (Verma et al., 2015).

The CDC (2017a) has a Colorectal Cancer Control Program (CRCCP) that helps states and tribes across America increase CRCS by awarding \$22,800,800 to 24 state health departments, six universities, and one American Indian tribe. Each recipient of this grant must target their services towards: 1) adults 50-75 years of age without symptoms; 2) low income, or under or uninsured, racial/ethnic groups disproportionately affected or geographic barriers to screening; and 3) at risk populations (CDC, 2017a). North Dakota was not one of the states that was chosen as a recipient of this award.

#### **Theoretical Framework**

The Doctor of Nursing Practice (DNP) degree prepares individuals to demonstrate knowledge, synthesis, and skill refinement through the completion of the DNP project (Moran, Burson, & Conrad, 2017). DNP graduates continue to help shape the profession of nursing after graduation to help improve healthcare outcomes to optimal levels (Moran et al., 2017). Nurse Practitioners can provide leadership throughout the community by collaborating with primary

care and public health agencies to improve health policy and health outcomes for all adults, 50-75 years of age, to help prevent CRC through CRCS.

There are twelve essentials that must be present in a DNP accredited program (AACN, 2006). The essential that correlates the strongest with this project is the Essential II, which is organization and systems leadership for quality improvement and systems thinking which improves client and health care outcomes (Moran et al., 2017). Nurse Practitioners can provide leadership throughout their place of work and community through practice change initiatives.

Nursing theories guide nursing practice by providing implications for instrument development, testing theories through research, and developing nursing practice strategies (Smith & Parker, 2015). Research that does not include a theory or model is more likely to have inaccurate data and disconnected information (Fain, 2015). Evidence based practice (EBP) models for change are necessary to help guide the implementation of EBP improvement projects (Dang et al., 2015). A theory for practice and EBP model for change was discussed for implementing CRC awareness and screening for adults' ages 50-75 years of age during influenza vaccinations in primary care and public health clinics.

#### The Health Promotion Model (Revised)

The theory for practice that was applied to the evidence-based practice (EBP) improvement project was Nola Pender's Middle Range Theory, the Health Promotion Model (HPM) (Appendix B). Permission to use the HPM was obtained by Pearson Education, Inc., New York, New York (Appendix C). The HPM was derived from the social cognitive theory and the expectancy-value theory that provides a nursing perspective of holistic human functioning (Pender, Murdaugh, & Parsons, 2015). The World Health Department (WHO) (2017, para. 1) defines health promotion as "the process of enabling people to increase control over, and to improve their health." Screening for a disease is a cornerstone of health promotion (Frazier, 2004). Multiple studies have used the HPM to guide screening aspects of health promotion. Frazier utilized the HPM to guide her dissertation on finding a noninvasive way to screen for CRCS, such as screening for any symptoms of CRC and utilized questionnaires to identify CRC symptoms (Frazier, 2004).

The HPM integrates nursing and behavioral science perspective along with factors that influence health behavior and offers a guide to explore complex biopsychosocial processes that motivate individuals towards health seeking behaviors (Pender et al., 2015). The factors that are included in the HPM are broken down into three main groups, which include individual characteristics and experiences, behavior-specific cognitions and affect, and the behavioral outcome (Pender et al., 2015). A fifteen-question survey was created utilizing this model using demographic data, yes/no questions, closed ended questions and Likert scales. The HPM theory guided the creation of this project along with formulating the survey.



*Figure 1*. Nola Pender's Health Promotion Model 1.Image retrieved from Pender et al. (2015, p.35). Reprinted by permission of Pearson Education, Inc., New York, New York.

#### **Individual Characteristics and Experiences**

The factors that are included in the individual characteristics and experiences include prior related behavior, and personal factors. Prior behavior is the best predictor for the individual's likelihood of participating in health-promoting behaviors (Pender et al., 2015). Understanding an individual's prior health-promoting behaviors can help Nurse Practitioners build positive health-promoting behaviors by teaching the individual the benefits of the healthpromoting behaviors and how to overcome obstacles to achieving the behavior. Personal factors include biologic, psychologic, and sociocultural (Pender et al., 2015). The personal factors that were included in this project include age, race, gender, and perceived health status. Prior CRC awareness and screening helped determine what educational resources were needed to help encourage a health-promoting behavioral change or sustain the current health-promoting behavior for adults who were 50 to 75 years of age.

#### **Behavior-Specific Cognitions and Affect**

The factors that were included for behavior-specific cognitions and affect included identifying the individual's perceived benefits of action, perceived barriers to action, perceived self-efficacy, activity-related affect, interpersonal influences, and situational influences (Pender et al., 2015). Measuring these variables was key in understanding if a health-promoting intervention led to a health-promoting behavior change. The perceived benefits of action in CRCS included preventing, detecting, treating cancer early, and having peace of mind. The perceived barriers to CRCS in the survey included the cost of screening, access to care, knowledge deficit of colorectal screening options, and embarrassment to talk about it. Understanding a person's self-efficacy is essential to plan a course of action for a healthpromoting behavior. Understanding how one perceives their overall health and how interested

they are in CRCS helped guide the plan for health-promoting behavior change. Identifying how an individual would like to receive information through either interpersonal influences or situational influences helped develop effective strategies for health-promoting behavior changes (Pender et al., 2015). Influences for CRCS could include receiving information at a FluFit clinic, health care clinic, work place, in the community, or from family and friends.

#### **Behavioral Outcomes**

The factors that were included in the behavioral outcomes included a commitment to a plan of action, immediate competing demand and preferences, and the health promoting behavior (Pender et al., 2015). Understanding how likely adults, ages 50 to 75 years, would start or continue CRCS helped determine their commitment to plan of action and health-promoting behavior. Understanding why or why not they wouldn't start or continue screening was also essential in predicting a behavior change and obtaining positive health outcomes for the individual that was aided by the project survey (Pender et al., 2015). Demographical information was also helpful to better understanding the individual's behavior outcomes.

#### The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

The EBP model for change that was utilized was the Iowa Model Revised: Evidence Based Practice to Promote Excellence in Health Care. The Iowa Model provided a guideline for implementing EBP practice change to provide optimal patient outcomes (Dang et al., 2015). There are ten steps along with feedback loops throughout to help guide the process of practice improvement in clinical and administrative settings (Dang et al., 2015). The steps of triggers, purpose, prioritization, team formation, assembling, appraising and synthesizing research, having sufficient evidence, designing and piloting practice change, adoption and ultimately integrating and sustaining practice change were applied to the practice improvement project.

### **Triggers and Opportunities**

The first step was to identify a triggering issue or an opportunity for improvement (Iowa Model Collaborative, 2017). Triggers can be identified by questioning current practices in which a clinical problem or knowledge deficit may be (Dang et. al, 2015). Colorectal cancer is preventable, detectable, and treatable when found early, yet only 35% of the population of ND, between the ages of 50-75 years, are participating in colorectal screening (NDCRC, 2017). About 60% of the colorectal deaths in ND would decrease if everyone between the ages of 50-75 years old had regular colorectal screenings (NDCRC, 2017). The opportunity exists to provide an intervention to help increase screening rates of CRCS to help improve patient outcomes related to colorectal cancer.

#### Purpose

The second step was stating the purpose, or the question to help target the approach to synthesizing the body of evidence (Iowa Model Collaborative, 2017). The purpose of the project was to increase public participation and awareness of colorectal cancer screening specifically in the rural ND town. Collaborating helped to identify if providing colorectal screening through public health and primary care effectively provides a mode of intervention to help increase CRCS rates.

#### **Priority**

The third step was identifying if the topic is a priority (Iowa Model Collaborative, 2017). After communication with the administrator from the rural Public Health Department and the clinical nursing supervisor at the Primary Health Clinic, incorporating colorectal screening and awareness during influenza vaccinations was established as beneficial to both facilities and stakeholders were formed.

#### **Team Formation**

Establishing a team was necessary to develop, implement, and evaluate practice change that consisted of key stakeholders (Dany et al, 2015). Key stakeholders were formed in conjunction with the step above. Committee members were selected based on their area of interest, areas of expertise, and their background. Key personal established at the rural ND Primary Care and Public Health facilities included an administrator, clinical nursing supervisor, health care providers, nursing staff, and clerical staff.

#### Assemble, Appraise, and Synthesize Body of Evidence

The next step was to assemble, appraise and synthesize the body of evidence (Iowa Model Collaborative, 2017). A literature review was conducted that included pathophysiology of colorectal cancer, stages of colorectal cancer, signs and symptoms of colorectal cancer, screening methods for colorectal cancer, CRC morbidity and mortality rates, contributing factors associated with colorectal cancer, barriers to CRCS, and increasing CRCS and awareness. The gathered information was appraised and synthesized. The FluFIT program was reviewed by the NIH and the AHRQ, with both organizations finding significant evidence that the FluFIT program was effective at increasing CCS rates (NIH, 2017; AHRQ, 2014). A multisite, randomized trial measured the effectiveness of a FluFIT program that showed an increase across all sites in screening rates for people who have not had CRCS (Potter et al., 2013). A randomized clinical trial compared the repeat annual CRCS rates for adults, ages 50 to 64 years of age, over a three-year period (Singal et al., 2017). The results validated that mailing invitations for colorectal screening was promising at increasing repeat annual colorectal screening (Singal et al., 2017).

### **Sufficient Evidence**

The next step was to identify if sufficient evidence was gathered to implement the proposed plan of action (Dang et al., 2015). Accomplishing this step occurred through consulting with committee members during the proposal meeting, the literature review, and from stakeholders. All suggested changes and feedback given were incorporated to improve the outcomes of the project.

#### **Design and Pilot the Practice Change**

The next step was to identify the outcomes and implement the EBP project (Dang et al., 2015). The project objectives were to: 1) increase the number of individuals receiving information on CRC ages 50-75 who present for influenza vaccination; 2) offer a survey to people ages 50-75 to determine if they have had colorectal screening and what their awareness is for colorectal cancer; and 3) Provide 100 FIT test kits to unscreened population ages 50-75 years old.

### Adoption

The adoption stage occurred when change was appropriate in practice (Iowa Model Collaborative, 2017). After designing and piloting the practice change, the co-investigator needed to determine if there was an increase in CRCS rates. Adoption would occur if the results were beneficial for both the public health and primary care collaborating parties.

#### **Integrate and Sustain the Practice Change**

The next step to was to integrate and sustain the practice change, which involves identifying and engaging key personal, hardwire change into system, monitor for key indicators through quality improvement, and reinfuse as needed (Iowa Model Collaborative, 2017). If the implementation was found to improve CRCS rates for adults, ages 50-75 years, then future

collaborations with public health and primary care could occur to improve the health outcomes throughout the community. Continuing research similar to this project could help identify other interventions that could help increase CRCS rates.

## **Disseminate Results**

The last step was to disseminate the results of the practice improvement project (Dang et al., 2015). Nola Pender's HPM provided a framework to help disseminate the results of the project as the individual characteristics and experiences, behavior-specific cognitions and affect, and the behavioral outcome could all influence the likelihood of engaging in health-promoting behaviors such as CRC screening. The HPM has been used in various studies and projects that focus on health promotion, such as screening for a disease process (Frazier, 2004). The dissemination of the results occurred through the dissertation, 2 poster presentations, and presenting of results to stakeholders. Stakeholders from the intended facilities were informed via an electronic e-mail. The co-investigator also plans to publish an article regarding the practice improvement project to an appropriate journal. The FIT results and appropriate follow up was communicated to the individuals through the health care providers at the Public Health Department and Primary Care Clinic in the rural ND town.

#### **CHAPTER THREE. PROJECT DESIGN**

Multiple researchers have determined that implementing CRCS on a population-based approach throughout a community has been beneficial to increase rates of CRCS (AHRQ, 2014; NIH, 2017; Potter et al., 2013; Verma et al., 2015; Weiner et al., 2017). Colorectal cancer becomes more of a risk for both men and women as they age, and the USPSTF recommends that CRCS begin at age 50 years to help prevent, detect, and treat CRC early (USPSTF, 2016). Providing primary prevention through colorectal education along with offering secondary prevention through FIT kits at influenza clinics presents an opportunity to target the unscreened population and increase the rates of people being screened for colorectal cancer. After careful critical appraisal of the evidence, a plan was developed to implement CRC awareness during influenza vaccinations for the public in a community. The plan for this project included collaborating with one of the Primary Care Clinics in the community and the Public Health Department in the rural ND town to increase colorectal screening rates.

#### Methodology

Clinical Practice Guidelines (CPG) help clinicians incorporate evidence-based research into their practice (Melnyk & Fineout-Overholt, 2015). The recommendations from the USPSTF guidelines was utilized for this project. Applying the CPG for CRCS in public health and primary care settings can help to increase the CRCS rates in ND.

Clinical expertise is necessary to provide quality evidence-based knowledge and recommendations (Melnyk & Fineout-Overholt, 2015). Meetings with the Public Health Department and chosen Primary Care Clinic were held at each organization's office, face-to-face with the co-investigator, to determine community needs. The topic of CRCS was determined to be a common need that could be collaborated on. A committee was formed to develop the

proposal and garner feedback for IRB approval and implementation. After IRB approval was granted, further meetings with project stakeholders in the community (NDCCRT, Public Health, and Primary Care) to decide which influenza vaccination sites were to be used within the community from each organization and how long to implement the project. No additional IRB process was necessary through either the Public Health Department or the chosen Primary Care Clinic. The stakeholders and co-investigator determined two sites between the Primary Care and Public Health organizations to target and distribute educational materials and possible FITs to potential participants during the 2017/2018 influenza season. The two sites were located at the Primary Care Clinic and at the Public Health Clinic. The FluFIT intervention was not implemented at other locations, such as workplaces and community influenza blitzes due to a decrease in number of clerical staff present to assist with the project at these locations. The NDCCRT workgroup leader (American Cancer Liaison for the project) was the Health Systems Manager at the American Cancer Society in Fargo, ND and was in communication with the administrator of the Public Health Clinic and the co-investigator to help structure the FluFIT implementation process by offering educational brochures to utilize for the project, providing links for the FluFIT program that has educational information for staff training, along with allowing the use of images from the NDCCRT to be used in presentations. The NDCCRT is a statewide coalition made up of various health organizations that is co-lead by the ACS and the North Dakota Department of Health (NDDOH) that is located in Bismarck, ND. The Clinic Nursing Supervisor of the Primary Care Clinic was assisting with this project as the Primary Care Liaison.

Meetings for staff and nursing education regarding the project took place during already scheduled staff meetings in designated meeting rooms in each organization, led by the co-

investigator and the Primary Care Liaison at the Primary Care Clinic and the Public Health Liaison at the Public Health Department regarding implementing CRC brochures, surveys, and FIT kits during influenza vaccinations. Staff training followed the recommendations with permission from Dr. Potter who helped found the FluFIT program located in Appendix I (UCSF, 2016). The staff involved at the Primary Care Clinic included nurses and clerical staff that were present during the influenza vaccinations and health care providers entered orders for the FIT screening and received results to follow-up with participants. The staff involved at the Public Health Department included clerical staff and nurses that provided influenza information and vaccinations and FIT tests at the clinic.

Educational brochures that were donated from the ACS and NCCR were distributed to potential participants who presented to the influenza vaccination sites (Appendix E). Permission to use the brochures on CRC was given to the co-investigator by the ACS Liaison, on August 31<sup>st</sup>, 2017 via e-mail (Appendix F). The ACS liaison was also the Co-Lead for 80% by 2018 initiative in ND. Brochures were donated from the ACS to distribute at the influenza vaccination sites. The goal was to have approximately 500 brochures handed out during this project to adults, ages 50-75 years. The goal of 500 brochures was determined by both Primary Care and Public Health to be an attainable number for this project, as the median age in the rural ND town is 39.6 years of age. The brochures were disturbed evenly to each site with 250 at the Public Health influenza vaccination sites. According to the Public Health Liaison, the rural ND town provides approximately 3,000 vaccinations through the Public Health Department each year between all of their sites, either in the department clinic or throughout the community, which could include 50 different sites throughout the county, including work places in the ND town.

The participant survey was developed by the co-investigator with input from the Public Health Liaison and based on the literature as well as guided by Pender's Health Promotion Model (HPM) to fit the needs of this practice improvement project. The survey questions were based on the HPM using demographic data, yes/no questions, closed ended questions and Likert scales (Fain, 2013). The survey helped measure the participant's characteristics, behaviorspecific cognitions and affect, and the behavioral outcome, such as the likelihood of getting screened for CRC (Pender et al., 2015). The survey was used to identify if the individual has had CRCS, such as a FIT within the past year or a colonoscopy within the past 10 years. The survey was offered at both of the influenza vaccination sites in the project for adults, ages 50-75 year, by nurses and staff already assisting with the influenza clinics.

Approximately 100 FIT kits were available to be offered during this project that were donated from the Primary Care Clinic for the purpose of the project, with a goal of 50 being handed out in Primary Care and 50 handed out in Public Health. The number of FITs was determined by both the Primary Care Clinic and Public Health Clinic to be attainable and were available at the time of the project. The FIT kits were offered to adults who had not yet had colorectal screening, such as a FOBT or FIT within the last year or a colonoscopy within the last ten years. Potential participants also needed to be between the ages of 50 to 75 years old and who preferred the Primary Care Clinic chosen in the project. The FIT kits came in a prepaid envelope with instructions on how to complete the test with patient information sheets to complete prior to mailing back the sample for testing. No participant identifiers or actual FIT testing results were collected in the project, rather just the number of distributed FITs and the return rates in aggregate form for comparison between the Public Health Department and chosen Primary Care Clinic.

During the actual FluFIT implementation, reception screened the potential participant's age through the electronic health record (EHR) or medical form that had already been completed for the influenza vaccination. If the patient was between 50 to 75 years of age, the receptionist (at all sites) offered the cover letter and possible project survey to complete by following the oral script provided (Appendix L). A cover letter (Appendix M) was attached to the survey for informed consent. Participation was voluntary. If the participant was willing, reception then handed the participant the cover letter that described the informed consent and attached survey if participants were willing. Participants were to keep the informed consent sheet for reference of the project and contact information if any questions or concerns arose. Consent was voluntary and indicated by participants by filling out the survey and handing the survey to the nursing staff. The nurse then determined if the survey results indicated possible FIT testing needs and discussed the possibility of screening by offering the patient to take home a FIT test that same day if the participant met the criteria (between the ages of 50-75 years, and had not yet had a FOBT or FIT testing done within the past year or a colonoscopy within the past 10 years) as following recommendations from the ACS (2017a). If the patient was eligible for CRCS and was interested, the nurse provided the patient with the cover letter explaining the test and information should the patient have any questions at any time, that participation was voluntary, and that he/she could decide not to turn the FIT in at any time. If the patient agreed, the nurse would then place a standing order within the electronic health record (EHR) that populated the patient in his/her existing chart within that same healthcare organization as the designated Primary Care Clinic to create a tracker/order number for this screening test. Then, the same nurse that distributed the FIT to the patient with his/her influenza vaccine would provide the FIT to take home along with the cover letter information (Appendix N) as a reference for the participant.

Once the nurse completed recording the survey information into the chart, the nurse placed the survey at a designated folder located at each nurses' station at each site. The co-investigator then collected the surveys at the end of the project for evaluation and kept the information in a locked file. No one else had access to the hard copy survey results and there was no identifiable information on the collected surveys. Both nursing and reception would be able to answer participant questions if needed at all the influenza vaccination sites.

When the FIT results came back, the same order number was already attached and the EHR system was able to track that this was a FIT provided at the influenza clinic versus ones from regular providers at the Primary Care Clinic, as the order was entered as a standing order and not one entered by a provider, such as what happens when the patient is provided a FIT screening test at the provider office after discussing this with the provider in other situations when a patient goes into the clinic, rather than at an influenza vaccination site. When the Public Health Department in this project had a patient who received a FIT, the nurse faxed that patient's information, such as their name, date of birth, and primary health care provider to the Primary Health Clinic where the nurses put in a standing order for that patient in the same way as noted above to be tracked as a FIT provided at the influenza clinic and not one provided in the provider office. The Primary Care Clinic was then responsible for contacting the patient to discuss the results of their FIT along with any potential follow-up testing required if needed. The providers placing orders and receiving results via EHR documentation were then tracked by an internal evidence source, by the Primary Care Liaison, that was already in place and could be used to track the FIT kits that were handed out during influenza vaccinations. The Primary Care Liaison would track the information and report the aggregate data of only the FIT return rates to the coinvestigator, therefore no additional permission was needed to gain access to the information, as

the actual individual results were not part of the project. The Primary Care Clinic's provider(s) would then share the results with the participant and form a plan, if results were positive, for further testing through the chosen Primary Care Clinic. The nursing staff at the Primary Care Clinic were to provide reminder phone calls at one week after receiving the FIT and send a letter out one month after receiving the FIT to ensure follow-up.

The co-investigator did not receive any of the actual individual FIT results from participants, rather only the return rates in aggregate form from each of the influenza vaccination sites from participants. The Primary Clinic Liaison monitored the return rates and submitted a copy of them to the co-investigator at the end of the project.

During the second year of implementation, which was during the 2018 influenza season, the Public Health Site Administrator voiced concerns that the influenza vaccination site was experiencing a large volume of adults presenting to the clinic for their influenza vaccination, which was creating more difficulties for reception to direct potential participants in the project to nursing or answer questions. To alleviate stress from the front desk staff, per the Public Health Department request, the co-investigator created a poster to place in the Public Health Department influenza vaccination site displaying how to participate in the project, such as more information regarding the project, colorectal cancer, and how to be screened during the influenza vaccination site. The Public Health Site Administrator felt this would relieve a lot of stress by having the poster and surveys for potential participants to take (located under the poster in a pile) if he or she chose to fill the survey out and where to hand the completed surveys to the nurse completing their influenza vaccination. The poster that was created and displayed is located in Appendix K.

#### Resources

The resources that were utilized in this project included support and approval from the personnel involved, such as the site liaisons at Public Health Department and the chosen Primary Care Clinic. In addition, time commitments, technology of the EHR already being used at the Primary Care Clinic site developed by the Primary Care Liaison, staff education for reception, staff, and nurses at both sites, donations of the FITs from the Primary Care Clinic and the donation of brochures from the ACS liaison were involved. The University of Iowa Hospitals and Clinics provided permission to use the Iowa EBP Model Revised to help guide the project and site within the dissertation (Appendix J).

The time involved preparing for this project included the time spent collaborating with key stakeholders at both organizations to address how and when to implement the project, along with staff education during meetings prior to implementation of the FluFIT clinics. No extra compensation was provided by either the Public Health Department or chosen Primary Care Clinic for staff, nurses, providers, or key stakeholders for time given to the project. Communication took place in face to face meetings, via e-mail and phone conversations at each site involving clerical staff, nurses, providers and the liaisons for each site. No additional funding for reimbursement of time or the space provided during meetings at each site was necessary. Conference rooms already located at each site were available for meetings and collaboration.

Funding for this project was relatively minimal. The educational brochures were donated by the ACS Liaison. The FITs and technological support for the tracking the results from the FITs were provided by the Primary Care Liaison. Educational meetings for all nursing and clerical staff involved at both sites took place during already scheduled staff meeting times, thus not impacting the cost of productivity at either site. Minimal cost for the co-investigator involved

printing off the surveys for the project. No monetary incentive was provided to anyone participating in this project.

#### **Protection of Human Subjects**

The benefits and harms of CRC awareness and screening in Public Health and Primary Care for adults ages 50 to 75 years were incorporated into the project. The USPSTF (2016) supports the main benefit for CRCS is that screening reduces the mortality rate of CRC in adults ages 50-75 years. The main harm of detecting and early intervention was found to be the potential harm in awaiting the results, use of invasive procedures, and the preparation that the individual does prior to a procedure, depending on screening method chosen by the individual (USPSTF, 2016). The potential harm considered for potential participants in this project was possible anxiety in awaiting FIT results and the testing did not require any invasive procedures for the purposes of this project. Potential participants were on a volunteer basis and informed consent was provided. Participants were provided a copy of the informed consent to keep for reference and contact information if needed.

Another potential risk that participants could have encountered was the potential for positive test results that could potentially cause psychological harm and potential future financial cost. To protect the rights of the participant and minimize risks, an Institutional Review Board (IRB) approval was obtained through the North Dakota State University (NDSU) prior to implementing this project. The potential risks were described to each potential participant on the informed consent page, along with contact information should there be concerns or questions.

Additional IRB approval was not required for either the Primary Care site or the Public Health site involved in this project based on their facility policies. Formal documentation from both sites stating no IRB approval was obtained (Appendix O). The IRB approval from North

Dakota State University (NDSU) was obtained for this project on 10/12/17 (Appendix P). A Continuing Review Report was completed and approved by the NDSU IRB on 9/26/18 (Appendix Q). An IRB amendment was approved for utilization of a poster to be displayed at the Public Health Department on 10/01/18 (Appendix R).

Cover letters were created, and approved for use by NDSU's IRB, for both the survey and FIT distribution (Appendix M & N). The information on the cover letters included explaining the project in detail along with stating that participating in this project was completely voluntary and that by completing the survey and handing the survey in along with turning their FIT in (if applicable), that they gave consent to participate in this project. Contact information for the both the primary investigator and co-investigator along with NDSU's IRB contact information was located on the cover letter in case the potential participant had any questions regarding the project.

#### Timeline

The project was implemented during the 2017 and 2018 influenza seasons, and the timeline was as follows:

- 1. Proposal Meeting on 10/18/17
- 2. IRB approval on 10/12/17
- 3. IRB continue review report on 09/26/18
- 4. IRB amendment on 10/01/18
- 5. Meetings at the Public Health Clinic on 11/08/17 and 08/31/18
- 6. Meetings at the Primary Care Clinic on 11/07/18 and 08/28/18
- 7. Implementation year one took place on 11/08/17-02/01/18
- 8. Implementation year two took place on 09/01/18-10/31/18

- 9. Dissemination to stakeholders took place during face-to-face meetings and the executive summary was shared via e-mail
  - a. Public Health Clinic 3/12/19 and Primary Care Clinic on 3/15/19
- 10. Final defense to committee members took place on 03/11/19

#### **CHAPTER FOUR. EVALUATION**

Methods for evaluation were identified to measure the effectiveness of the objectives. Each objective was measured to assess if the practice improvement project met the goals to increase CRC awareness and CRCS screening throughout a rural town in ND.

#### **Evaluation Methods**

The first objective of the project was to increase the number of individuals receiving information on colorectal cancer and screening options for those ages 50-75 years of age by distributing informational brochures when present for influenza vaccination at the Public Health Department or the Primary Health Clinic during the 2017 and 2018 influenza seasons. The number of distributed educational brochures left over was one method of determining the extent to how many individuals in the community were impacted by this project. The number of colorectal cancer awareness brochures distributed during influenza vaccinations at the Public Health and Primary Care Clinic sites combined were tracked by determining how many brochures were left over from each site at the end of each the 2017 and 2018 influenza seasons to get the project total after the final conclusion of implementation phase on 10/31/18. That total number was compared to the original 500 available to determine exactly how many were distributed during both the influenza 2017 and 2018 seasons combined.

#### **Objective Two**

The second objective was to identify barriers to screening within the rural ND town's population by developing and implementing a survey for those ages 50-75 years of age present for the influenza vaccination at the public or Primary Health Clinic during the 2017 and 2018 influenza seasons to aide future planning for improved screening processes through the Public Health Department. Measuring the second objective was accomplished by having participants

complete a survey, if meeting inclusion criteria, to determine if the individual had already been screened for colorectal cancer and what his or her awareness was with a survey by measuring his or her characteristics and experiences; perceptions surrounding education and screening methods; and an indication of the likelihood of getting screened for colorectal cancer in the future (Pender et al., 2015). The quantitative and qualitative data was compiled and compared which included demographic data, yes/no questions, closed ended questions, Likert scales and one open-ended question.

#### **Objective Three**

The third objective was to positively impact screening rates for CRC in North Dakota by supplying 100 donated FIT's and distributing these during the influenza vaccination sites at a Primary Care Clinic and Public Health Department to individuals ages 50-75 years of age who had not had CRC testing such as a FOBT or FIT within the last year or a colonoscopy within the last 10 years during the 2017 and 2018 influenza seasons, as this reflected the ACS guidelines. The third objective was measured by tracking the number of people who returned their FIT kit for testing, with a goal of handing out 50 FITs at both the Public Health Department and Primary Care Clinic influenza vaccination sites, for a total of 100 FITs total to be provided to potential participants. The number of FITs distributed that were returned (mailed back in for results) were tracked via the EHR at the Primary Care Clinic by the Primary Care Liaison involved in the project. The aggregate return rate results were compared with how many FITs were handed out at each site and how many were returned in from each site.

### CHAPTER FIVE. RESULTS AND DISSUSSION<sup>1</sup>

#### **Objective One Results**

The first objective was to increase the number of individuals receiving information on CRC and screening options for those ages 50-75 years of age by distributing informational brochures when present for influenza vaccination at the Public Health Department and the Primary Health Clinic during the 2017 and 2018 influenza seasons. Exactly 153 brochures from the Public Health Department site remained after the completion of the project, resulting in 97 brochures that were distributed at the Public Health Department site to people who presented for the influenza vaccine. The Primary Health Clinic site distributed all their available brochures by the end of the project, indicating that 250 brochures were handed out total. All the site totals combined indicated that 347 people received educational information on CRC and screening options during the 2017 and 2018 influenza seasons. The Public Health Department and Primary Care Clinic kept the remaining brochures in between influenza seasons, and the totals between each year were not calculated.

#### **Objective Two Results**

Objective two of the project was to identify barriers to screening within the rural ND town's population by developing and implementing a survey for those ages 50-75 years of age present for the influenza vaccination at the Public Health Department or Primary Health Clinic during the 2017 and 2018 influenza seasons to aide future planning for improved screening

<sup>&</sup>lt;sup>1</sup> The material in this chapter was co-authored by Laura Bond and Dr. Heidi Saarinen. Laura Bond had primary responsibility for collecting samples in the field and for interviewing users of the test system. Laura Bond was the primary developer of the conclusions that are advanced here. Laura Bond also drafted and revised all versions of this chapter. Dr. Heidi Saarinen served as proofreader and checked the math in the statistical analysis conducted by Laura Bond.

processes through the Public Health Department. The goal of this objective was to use the survey to identify if the individual had CRCS, such as with a FIT within the past year or a colonoscopy within the past 10 years and what his or her awareness was of CRC and screening options. Approximately 11 participants at the Primary Health Clinic and 20 participants at the Public Health Clinic filled out the survey for a total of 31 participants. Exactly 29 surveys were from the first year of implementation and two surveys were from the second year of implementation. The two surveys were completed by participants at the Public Health Department prior to the poster implementation that began on 10-01-18. Table 2 below displays the quantitative data from the survey.

### **Year One Implementation**

The Primary Care Clinic had 11 participants complete and turn in surveys during the first year of the 2017 influenza season, or the first year of the project. The Public Health Department had 18 participants complete and turn in surveys during the first year of the project. Implementation of the first year occurred from 11-09-17 through 02-01-18.

#### Year Two Implementation

Implementation of the second year took place from 09-01-18 through 10-31-18. The Primary Care Clinic had no further surveys collected during this implementation timeframe. The Public Health Department had two participants complete surveys between 09-01-18 through 09-31-18. On 10-01-18, a poster was displayed in the lobby of the Public Health Department to help alleviate stress from the clerical staff due to high volumes of adults presenting to the site for influenza vaccinations and limited time to inquire after potential participants. The poster displayed the project, CRC education, and screening options. Surveys were located underneath the poster for potential participants to take and return if applicable. After implementation of the poster, no further surveys were completed at the Public Health Department.

Table 1

# Survey Results for Objective One

	Answer/Response	Mean (%)
Question	(N=31)	
Completed at the Primary Health Clinic	11	35.5%
Completed at the Public Health Clinic	20	64.5%
Female	18	58.1%
Male	13	41.9%
Ethnicity		
Caucasian	31	100%
Hispanic/Latino	0	
Black/African American	0	
American Indian	0	
Asian/Pacific Islander	0	
Other	0	
Have you ever had colorectal screening done? If so, when and which	tests?	
Yes	26	83.9%
No	5	16.1%
Stool testing (at home kits)	0	
Procedure (colonoscopy, sigmoidoscopy, CT scan)	26	83.9%
Do you have Private Health Insurance?		
Yes	26	83.9%
No	2	6.4%
<b>Do you have Medicare?</b> (Only 8 participants answered this question)		
Yes	6	75%
No	2	25%
Has your Primary Care provider talked to you about CRCS?		
Yes	27	87.1%
No	4	12.9%
Did you know that you can complete colorectal screening at home?		
Yes	24	77.4%
No	7	22.6%
Have you, a family member, or friend been diagnosed with colorectal	cancer?	
Yes	7	22.6%
No	23	77.2%

Question	Answer/Response (N=31)	Mean (%)
Circle any or all benefits that CRCS offers you	(1( 51)	
Prevent colorectal cancer	20	21.07%
Detect colorectal cancer	28	29.47%
Treat colorectal cancer	20	25.26%
Peace of mind	22	23.15%
Not sure	1	1.05%
Circle any or all of the following that might keep you from getting participants answered this question)	g screened (Only 7	
Costs too much to get screened	1	14.28%
I cannot get to a place to get screened	1	14.28%
I am not sure of what screening options there are	4	57.14%
I do not want to talk about colorectal screening	1	14.28%
How do you consider your overall health?		
Very healthy	6	19.7%
Healthy	21	67.7%
Somewhat healthy	4	12.9%
Not healthy at all	0	0%
How do you like to get information about your health? Circle top	choice.	
Clinic/Provider Office	29	80.55%
At your work place	3	8.30%
In the community (community center, Public Health office)	2	5.5%
Family & friends	0	0%
Facebook/Social Media	0	0%
Newspaper	1	2.70%
Radio	0	0%
All of the above	1	2.70%
How likely are you to start or continue CRCS?		
Very likely	22	70.9%
Likely	6	19.4
Somewhat likely	3	9.7%
Not likely at all	0	0%
Preferred Clinic?		
Primary Clinics Involved in Project	13	41.9%
Primary Care Clinic not Involved in Project	15	48.4%
Clinic out of town	1	3.2%
Was a kit given out?	0	0%

# Table 1. Survey Results for Objective One (continued)

The participants were asked to determine how likely they were to either continue CRCS or start CRCS followed by being asked to describe why or why not they would continue or start CRCS. Approximately 16 of the 31 participants provided a qualitative answer for why or why not they are going to continue or start CRCS, as described in Table 2 below.

Table 2

Qualitative Data from Survey Results: Why or why not continue colorectal cancer?

Theme	Qualitative Data
Prevention and Detection	"Prevention/Detection."
	"Necessary for cancer detection."
	"Simplicity of doing it and know I can
	prevent one of the many cancers."
	"Prevention/Detection."
	"Feel it is beneficial to prevent cancer."
	"I have a FIT test at home."
Personal or family history of an inflammatory bowel disease or colorectal cancer	"History of cancer in the family." "I have colitis" "Had a previous pre-cancerous polyp removed."
Staying Healthy	"I just want good healthcare for myself." "Smart to do." "Good healthy practice." "Easy test. I think it's important." "You start at age 50 and continue through life." "Peace of mind."

Most of the participants had already had CRCS; however, five of the 31 participants had not yet had CRCS. To better understand the results from those participants who had not yet had CRCS, Table 4 was created with just the results from the unscreened participants.

# Table 3

Question	Answer/Response (N=5)	Mean (%)
Female	2	40%
Male	3	60%
Ethnicity		
Caucasian	5	100%
Hispanic/Latino	0	
Black/African American	0	
American Indian	0	
Asian/Pacific Islander	0	
Other	0	
Have you ever had colorectal screening done? If so, when and which tests?	0	
Yes	0	
No	4	80%
Stool testing (at home kits)	1	20%
Procedure (colonoscopy, sigmoidoscopy, CT scan)	0	
Do you have Private Health Insurance?		
Yes	3	60%
No	2	40%
Do you have Medicare?		
Yes	1	20%
No	2	40%
Has your Primary Care provider talked to you about CRCS?		
Yes	1	20%
No	4	80%
Did you know that you can complete colorectal screening at home?		
Yes	3	60%
No	2	40%
Have you, a family member, or friend been diagnosed with colorectal ca	ancer?	
Yes	0	0%
No	5	100%
Circle any or all benefits that CRCS offers you		
Prevent colorectal cancer	2	20%
Detect colorectal cancer	3	30%
Treat colorectal cancer	2	20%
Peace of mind	2	20%
Not sure	1	10%

# Results from the Unscreened Participants

0	Answer/Response	Mean (%)
<u></u>	(N=5)	
screened	0	
Costs too much to get screened	0	
I cannot get to a place to get screened	0	
I am not sure of what screening options there are	4	80%
I do not want to talk about colorectal screening	1	20%
How do you consider your overall health?		
Very healthy	0	
Healthy	5	100%
Somewhat healthy	0	
Not healthy at all	0	
How do you like to get information about your health? Circle top cho	ice.	
Clinic/Provider Office	4	80%
At your work place	0	
In the community (community center, Public Health office)	1	20%
Family & friends	0	
Facebook/Social Media	0	
Newspaper	0	
Radio	0	
All of the above	0	
How likely are you to start or continue CRCS?		
Very likely	1	20%
Likely	2	40%
Somewhat likely	2	40%
Not likely at all	0	
Preferred Clinic?	0	
Primary Care Clinic Involved in Project	2	40%
Primary Care Clinics Not Involved in Project	3	60%

# Table 3. Results from the Unscreened Participants (continued)

One out of the five unscreened participants provided a description of why or why not they started CRCS. One of the participants indicated that he/she felt starting CRCS was a "smart to do." A table was not created to reflect the qualitative data due to only one response.

#### **Objective Three Results**

The third objective was to positively impact screening rates for colorectal cancer in North Dakota by supplying 100 donated FITs and distributing these during the influenza vaccination sites at the Primary Care Clinic and at the Public Health Department to individuals 50-75 years of age who had not had colorectal cancer testing, such as a FOBT or FIT within the last year or a colonoscopy within the last 10 years during the 2017 and 2018 influenza seasons. The goal of this objective was to hand out 100 FIT tests total with 50 at each site.

The third outcome was measured by tracking how many people received a FIT at both the Public Health Department and Primary Care Clinic sites by how many FITs were left over at the end of the project for each organization. The number of FITs that were returned for results were tracked via the EHR at the Primary Care Clinic involved in the project. The FIT return rate results were compared between sites and the total number helped to determine how many FITs were handed out at each site to better determine if there appeared to be a better return rate at either the Public Health Department or Primary Care Clinic organizations. However, no FIT tests were handed out at either site. Most of the adults 50 to 75 years of age eligible for a survey stated that they had had a colonoscopy within in the last 10 years. Out of the 31 participants surveyed, two participants were eligible for a FIT, as they had not yet had colorectal screening before, and preferred the primary clinic involved with the project. However, one of those two participants declined completing a FIT test and the other participant had a FIT test at home already from a previous visit with his or her healthcare provider. The participant that already had the home FIT was not included in the results data, as the participant did not receive the FIT at an influenza vaccination site for the purposes of this project.

#### **Results Compared to Literature**

The CDC (2018) states that 66.5% of women in ND completed CRCS compared with men at 62.3%; 65.3% of the screened population identified themselves as Caucasian; and the insured (65.3%) tend to complete CRC more than the uninsured (39.7%). The survey results from the practice improvement project had similar findings. Women were the majority in this practice improvement project (58.1%); 100% of the participants identified themselves as Caucasian; and all the participants who had completed CRCS in the past were insured. Most of the residents in ND who completed CRCS were between the ages of 65-75 years of age and from 2012 to 2016 and CRCS increased from 58.5% to 64.4% while the national average is 67.3% (CDC, 2018).

The FluFit program was effective at increasing CRCS in Clinics with high volume influenza vaccinations with having 14.8% increase in CRCS rates in a study that consisted of 4,653 participants (Potter et al., 2013). The clinics involved in this study saw multiple clients for influenza vaccination. During year one of the project the Primary Care Clinic reported that they gave 402 influenza vaccinations and the Public Health Clinic reported that they gave 3,301 influenza vaccinations for a total of 3,703 the 2017 flu season. During year two the Primary Care Clinic saw approximately 378 clients who received their influenza vaccination from September 1<sup>st</sup>, 2018 to October 31<sup>st</sup>, 2018, as reported by the Primary Care Liaison and the Public Health Clinic Liaison reported that they saw approximately 3,089 clients who received their influenza vaccination. The practice improvement project had a combined total of 7,170 people who presented to the clinic for influenza vaccination with a total of 31 people who participated in the practice improvement project.
#### CHAPTER SIX. DISCUSSION AND RECOMMENDATIONS

#### **Interpretation of Results**

The overall purpose of this project was to increase the number of individuals receiving information on CRC and screening options for those 50-75 years of age by distributing informational brochures when present for influenza vaccination at the Public Health Department or the Primary Health Clinic. Collecting information about current knowledge and reasons for getting screened or not getting screened for CRC in the rural ND town could aide future planning for improved screening processes through the Public Health Department and help to improve CRCS rates in ND, as well as strengthen collaboration for improved patient outcomes.

#### **Objective One**

The purpose of the first objective was to increase the number of individuals receiving information on CRC and screening options for those ages 50-75 years of age by distributing informational brochures when present for influenza vaccination at the Public Health Department or the Primary Health Clinic during 2017 and 2018 influenza seasons. This objective was met, as a combined total of 347 brochures were handed out which provided people with information about CRCS and awareness. The goal of the collaboration between the Public Health Department and Primary Health Clinic of distributing all 500 brochures was partially met, and likely could have been fully met had the project been implemented in the exact same manner for both influenza seasons.

Another purpose of this objective was to identify if handing out educational brochures at influenza clinics would be an effective way to increase knowledge of CRCS screening options and awareness. Exactly 97 brochures were handed out at the Public Health Department to people who presented for an influenza vaccination compared to 250 that were handed out at the Primary

Care Clinic. The Primary Care Clinic handed out 153 more brochures than the Public Health Clinic, suggesting that providing the information in the form of an educational brochure might be better received from a Primary Care Clinic setting. More research should still be completed in the future regarding screening education and distribution of FIT testing at influenza vaccination sites, as this project had lower overall participation rates compared with the Potter et al (2013) study which had 4,653 participants with a 14.8% increase in CRCS screening rates. Due to the smaller sample size of this study, the results cannot be generalized to a larger population.

#### **Year One Implementation**

The Primary Care Clinic had 11 participants complete and turn in surveys during the first year of this project. The Public Health Department had 18 participants complete and turn in their surveys during the first year of this project, showing more participation from the Public Health Department site in relation to actual project participation. Implementation of the first year occurred from 11-09-17 through 02-01-18. Implementation of the project later in the influenza vaccination season, which usually begins in early September, was thought to contribute to lower participation rates. Thus, discussion of implementing the following year to yield more results was pursued. The Primary Care Clinic and Public Health Department both were agreeable to implementing the project again during the following 2018 influenza vaccination season.

#### **Year Two Implementation**

Implementation for year two took place from 09-01-18 through 10-31-18. The Primary Care Clinic had no further surveys collected during this implementation timeframe and all the brochures had been distributed prior. The Public Health Department had two participants who complete surveys between 09-01-18 through 09-31-18. The decision to terminate the project on 10-31-18 was due to low participation rates and the Public Health Department site not having

reception staff approach potential participants any longer. During the second implementation timeframe, the Public Health Department Administrator voiced concerns that the clinic was experiencing a large volume of adults presenting to the clinic for their influenza vaccination which was making more time constraints and stressors for the front desk staff to direct patients of the project to nursing or answer questions. To alleviate stress from the front desk staff, a poster was created by the co-investigator and displayed in the Public Health Clinic to help encourage potential participants and direct them on how to participate in the project. The information provided on the poster included information regarding the project, colorectal cancer, and how to be screened. Rowe (2013) found that integrating a poster, along with other interventions, was helpful to increase knowledge, however, more studies are required to see if posters achieve knowledge enhancement.

The poster that was implemented on October 1<sup>st</sup>, 2018 as a supplementation for the clerical staff at the Public Health Department site, appeared to be non-beneficial from the results of this project. After implementing the poster, no one took brochures as there were 153 brochures at the Public Health Clinic prior to the poster and 153 brochures at the end of the project on October 31<sup>st</sup>, 2018. Based on this data, the co-investigator determined that advertising participation is not as effective as personal interaction in this community. During the timeframe that the poster was implemented, no further surveys were completed at the Public Health Department site. These findings could better support the fact that 18 surveys were completed in the first year when clerical staff were discussing the project and survey with the participants and no surveys were completed with only the poster and no verbal initiation; therefore, the results suggested that more passive means of participation encouragement was not as effective as more involved means, such as relational interactions between staff, nurses, and potential participants.

#### **Objective Two**

Objective two of the project was to identify barriers to screening within the rural ND town's population by developing and implementing a survey for those ages 50-75 years of age present for the influenza vaccination at the Public Health Department or Primary Health Clinic during the 2017 and 2018 influenza seasons to aide future planning for improved screening processes through the Public Health Department. The survey results helped to identify if the participants had CRCS, their awareness of CRC, and screening options for the 31 participants involved in this project. The goal was met, as the survey helped compile information regarding barriers and perceptions to better help aide future screening considerations for ND in this community.

The survey results also revealed that many of the participants have had colorectal screening, with colonoscopy screening the most frequent assessment. The Public Health Clinic had the most participants at 65.5% and the Primary Care Clinic with 35.5%. Knowing that the Public Health Clinic had more participants could suggest that utilizing a Public Health site could be beneficial for future projects, as this could be an efficient way to target a broad population.

Females completed more surveys than males in this project. The CDC (2018) states that women in ND tend to complete CRCS more than men and that less women are expected to die from CRC due to the increase in CRCS. A decrease in mortality for women is largely due to more women participating in cancer screening and having access to high-quality health care (CDC, 2018). Since the majority of the participants in this project were female, the results were consistent with the CDC's findings which could mean women in this community are participating in cancer screening and have access to CRCS through the primary care clinics.

Most of the participants had private insurance or Medicare while there were two participants who did not have insurance. Having insurance appeared to have a direct relationship with participating in CRCS or not. The literature review showed that lack of affordability and lack of insurance were also identified as barriers to CRCS (CDC, 2018; NCCRT, 2017).

Most of the participants, 87.1%, reported having a discussion with their primary care provider regarding CRCS on the surveys. A possible reason for this is that most of the participants had insurance, thus have had the coverage for medical expenses, such as annual wellness examinations, compared to the participants who might not have had annual wellness examinations due to not having insurance. Most of the participants had heard of at home CRCS, which could indicate ample opportunity to hear about options from their health care provider and that these discussions are occurring, and providers are providing education and options.

Most of the participants, 77.4%, had heard of at home stool testing for colorectal cancer, so most people in those surveyed are getting some type of education on CRCS. Most of the participants did not have a personal, family history, or friend that was diagnosed with CRC. The ACS (2017a) recommends that an individual with a family history should get screened at least by age 40 or 10 years before the age that their relative was diagnoses with CRC. Also, interesting to discuss the fact that no one surveyed had used an "at home" kit before, even though the majority have heard of an "at home kit". Of those participants that did participate, 5 (16.1%) had not yet had any screening, which was a great target population to reach that might not have been impacted had this project not been done in the community collaborative setting.

The qualitative data that was collected in the survey identified three key themes of why participants started or would continue CRC screening. The three key themes included: prevention and detection of CRC, personal or family history of an inflammatory bowel disease

(IBD) or CRC and staying healthy. Understanding the various themes for starting and continuing CRCS is beneficial to aide in future projects to help increase CRCS and awareness. The significance of the theme "prevention and detection" is that most participants identified they are aware that CRCS helps prevent and detect CRC. Offering CRCS throughout the community during influenza vaccination clinics could have helped provide access to CRCS throughout the community which could ultimately help prevent and detect CRC. The significance of the theme of "personal or family history of an IBD or CRC" demonstrates that some participants were aware of their increased risk for developing CRC in the future. Sharing education with the community regarding the associated risks of having a personal or family history of IBD or CRC could help impact the overall CRCS rates and ultimately detect and prevent CRC. Identifying the theme of "staying healthy" showed that participants in this community value their health and would like to stay healthy, thus be willing to undergo possible screening.

Only 3.2% of the participants were not sure of the benefits that CRCS can offer and 12.9% indicated they were not sure of the different types of CRCS. An indication for more CRC awareness exists in this ND town since there were participants who had never had CRCS done before who fell within the ages of 50-75 years old. This number may have been higher with higher participation rates and including the other primary care organization in the community. Most participants disclosed that they preferred to get their healthcare through the other major primary health care facility in the area that was not included in this project. Therefore, more participants would have likely been obtained had the other organization been involved in addition to the 31 participants that were involved in this project. Approximately three known participants could have participated in the CRCS that was offered in this project by having all of the local primary care clinics involved in this project.

Other reasons that might have kept participants from being screened as indicated in the survey results included the cost, not being able to get to a place to be screened, and not wanting to talk about CRCS with a 3.2% response rate in each category. The results were comparable to some of the barriers addressed by the NCCRT (2017) which include a rationalized avoidance and lack of affordability. Access to care is also a barrier that was identified in the results along with in the literature by Gupta et al. (2014). Increasing access to care and discussing cost options, such as lower cost screening like the FIT, would be an option to discuss with patients along with mainstreaming CRC awareness throughout the community to potentially alleviate these reasons for not completing CRC screening.

Overall, all the participants identified themselves as healthy, which ranges from "very healthy," "healthy," and "somewhat healthy." Most of the participants who have had CRCS done in the past have identified themselves as "very healthy", whereas the participants who identified themselves as "somewhat healthy" consisted of individuals who have not had CRCS done before. This correlation could mean that by having CRCS individuals consider themselves very healthy for staying up to date with current guidelines to help prevent CRC whereas individuals who have not had CRCS.

The most preferred way participants indicated that they would like to receive information about their health was through a clinic/provider office (93.5%). Other areas the participants indicated that they would like to receive health information in general was at their work place (9.7%), in the community (community center, public health office (6.5%), and the newspaper (3.2%). Other options that were each listed separately on the survey included receiving information about their health from family and friends, Facebook/social media, and through the radio, and none of the participants chose any of these options. Knowing how the public would

like to receive information about their health is key to promoting CRCS and awareness. Receiving information from a clinic or provider was the most indicated area. However, receiving health information at their place of work and in the community and Public Health Department office were also indicated to communicate health information. Increasing CRC awareness and education throughout the community and through Primary Care could be beneficial to target all the preferred ways to receive health information that could help increase CRCS rates.

All the participants indicated that they were "likely" to continue or start CRCS with answers ranging from "very likely," "likely," and "somewhat likely." The participants who are "somewhat likely" to start CRCS were the participants who have never had CRCS done before. These participants might have insurance or know what the CRCS options are which could have made the only "somewhat likely" response to complete CRCS compared to the "very likely" and "likely" participants since they either know about the CRCS options or have had CRCS done before. None of the participants indicated that they are "not likely at all" to start or continue CRCS. Understanding how likely participants are to make the behavior change (participating in CRC screening) could help the individual achieve their health goals and to live a life of optimal health and wellbeing.

#### **Unscreened Population**

The unscreened population (N=5) consisted of both men and women with men having the majority (60%) which is consistent with the results from the CDC in which they state that women participate in cancer screenings more than men do (CDC, 2018). All the participants had never completed CRCS, however, one participant had a FIT test at home that was received during a previous health care visit. Two participants identified that they did not have either private insurance or Medicare coverage, indicating that not having insurance could be a barrier to

CRC screening. Most of the unscreened participants indicated that their primary care provider had not talked about CRCS, indicating that increasing conversations about CRCS could have the potential for increasing CRCS rates. This is especially true for health care provider impact, as most preferred their health information come from them. The results from this project are similar to some of the reasons identified, by the CDC (2017) as to why people don't get screened for CRC which include a health care provider didn't tell them to get screened and/or they didn't have health insurance.

Forty percent of the unscreened participants were aware that they can complete CRCS at home. None of the unscreened participants indicated that they have had a personal, family history, or have a friend with CRC that could be a factor in their desire to be screened or receive more health information regarding CRC and awareness. More data would be needed to support this factor. Most of the unscreened participants identified detecting colorectal cancer as a benefit for screening (60%). Other benefits identified were prevention of CRC, treatment of CRC and peace of mind all had 40% answer rates. One of the unscreened participants was unsure of the benefits of CRCS (20%). The majority of unscreened participants identified that not knowing what the CRCS options are was what could be keeping them from having colorectal screening done (80%).

Most of the five unscreened participants identified their overall health as "healthy" and were either "very likely," or "likely" to participate in CRC screening. Two of the participants indicated that they are "somewhat likely" to complete CRCS. The majority would like to receive information about their health through a clinic/provider office with only one indicating they would like to receive health information through a community center/Public Health Clinic. While the Public Health Clinic had most of the participants, they appeared to receive information

about their health from a clinic/provider office. Collaborating with both Public Health and Primary Care to promote CRC awareness and screening options could potentially help individuals understand the benefits of CRCS and ultimately increase the CRCS rates.

#### **Objective Three**

The goal of this objective to hand out 100 FIT tests total with 50 at each site to positively impact screening rates for CRC in North Dakota was not met. Participants either did not meet the criteria to complete a FIT or they declined to accept a FIT, thus no FIT tests were given out during this project. The FIT tests were given back to the Primary Care Liaison at the completion of this project.

Out of the 31 participants surveyed, five participants were eligible for a FIT. However, the two participants who preferred the Primary Health Clinic involved in this project to be able to complete the screening did not complete CRCS because one did not want to complete a FIT test and the other participant had a FIT test at home already from a previous visit with his or her healthcare provider. The other three who were unscreened for CRC preferred the primary care clinic not involved with this project. Having both primary care clinics involved in this project could have helped increase the CRCS in this ND town.

#### Dissemination

The findings of this project were discussed with each organization involved, shared with the American Cancer Society Liaison, and discussed at the co-investigator's final defense for the practice improvement project. The practice improvement project was also presented at the following poster presentations:

- The 2018 NDSU College of Health Professions Poster conference
- The 2019 NDSU College of Health Professions Poster conference

The co-investigator hopes to target a broader audience by pursuing publication of an article regarding the practice improvement project and results. Publication of the practice improvement project could hopefully inspire other practitioners to continue in the efforts to increase CRCS rates by collaborating with multiple organizations in their community to fill the gaps of disparity.

#### **Relation to Pender's Health Promotion Theory**

Nola Pender's HPM was used to provide a framework to guide this practice improvement project. Since the HPM integrates nursing and behavioral science perspective along with factors that influence health behavior and offers a guide to explore complex biopsychosocial processes that motivate individuals towards health seeking behaviors, the HPM was applicable for this project as CRCS is a large part of health promotion (Pender et al., 2015). The factors that are included in the HPM are broken down into three main groups which include individual characteristics and experiences, behavior-specific cognitions and affect, and the behavioral outcome (Pender et al., 2015). The HPM theory guided the creation of this project along with formulating the survey. The survey questions that were created helped to identify the individual characteristics and experiences, behavior-specific cognitions and affect, and the behavioral outcome that could influence the likelihood of engaging in health-promoting behaviors such as CRC screening. Overall, the HPM was effective in identifying health promoting behaviors and identifying how likely the participants are to make a health behavioral outcome.

Resulting from the project, 31 participants from the rural ND community completed the survey identifying key information regarding their individual characteristics and experiences with CRC and screening, whether they participated in CRCS, how they perceived their overall health, and how likely they were to start or continue CRCS in the future. Many of the

participants indicated that they perceived themselves as healthy which could indicate that this community is interested in healthy behaviors allowing for improved behavior change, such as participating in CRCS.

Key areas that were identified included whether the participants had completed CRC screening, and if so, which screening; identified if they had insurance or not; identified if they had a personal or family history along with knowing anyone with CRC; identified if they were aware of CRC testing done at home; perceptions on barriers to screening; likelihood of starting or continuing CRC screening; what they identified as benefits of CRC; health perceptions; and how they would like to receive information about their health. All this information assisted both the Public Health Department and Primary Care Clinic to plan and coordinate future collaborations together to increase CRCS rates, as both organizations verbalized intentions to take the information found from the project into future planning for education and screening considerations.

#### **Relation to the Iowa Model**

The Iowa Model Iowa Model Revised: Evidence Based Practice to Promote Excellence in Health Care is used to improve practice through evidence-based practice triggers, purpose, prioritization, team formation, assembling, appraising and synthesizing research, having enough evidence, designing and piloting practice change, adoption and ultimately integrate and sustain practice change. Since, this practice improvement project occurred in two separate years, the Iowa Model was essential to help assemble, design, and sustain a practice change. The evaluation took place over two influenza seasons which helped identify what was working and was not working which helped develop another intervention, such as a poster for the Public Health Department site.

#### **Limitations and Future Recommendations**

The main limitation in this practice improvement project was that only one of the three primary care health organizations in the rural ND town participated in the collaborative project with the Public Health Department, mostly due to not having a contact or liaison at the clinic to assist with this project. Another factor is that the FluFIT was not offered at workplaces and influenza blitzes throughout the community in which this might have targeted a broader audience possibly leading to more participants in this project. According to the results from the survey, most of the participants preferred the other primary care health organization in the town that was not involved with the project. Having both organizations involved could have allowed at least three known participants involved in this project to be screened for CRC, and likely more. Including all the willing and applicable organizations in future collaborative projects would be recommended along with offering the FluFIT at workplaces and influenza blitzes. Another limitation in this project was that both the Public Health Department and Primary Care Clinic kept the remaining brochures in between influenza seasons, and the totals between each year were not calculated.

A limitation in year one of the project was in the time constraints for this project. Ideally, this practice improvement project should have been implemented at the beginning of the influenza season in 2017, which began in September. However, awaiting all the aspects of the project implementation, the practice improvement project was not actually implemented until November 2017 and went until February 2018. The disadvantage in implementing in November was the potential for missing unscreened potential participants during the months of September and October 2017.

A limitation during year two of the project was not having the Public Health Department site distribute the information in the same manner as the previous influenza season throughout the entire influenza season. The Public Health Department site distributed the information via the same manner as discussed in the project through clerical staff and nursing from September 1<sup>st</sup>, 2018 to September 28<sup>th</sup>, 2018. On October 1<sup>st</sup>, 2018 a poster was used in place of clerical staff to provide information regarding this project. After implementation of the poster, no brochures were taken, and no surveys were completed. The Public Health Liaison stated that people who present to the clinic for an influenza vaccination expect to receive their vaccination in a prompt manner and that completing the survey and discussing the results with the nurse could be a barrier as to why more people did not participate in this project. She recommended advertising for receiving health information such as CRC awareness along with receiving an influenza vaccination, so people are aware that they could receive other information about their health besides receiving their influenza vaccination.

According to the NDCCRT (NDCRC, 2019), approximately 22 organizations throughout ND participated in the "80% by 2018 Pledge." These organizations consisted of both primary care and public health organizations. The "80% by 2018" campaign ended on December 31<sup>st</sup>, 2018 and the results won't be available until 2020 to see if the 80% goal was met (NCCRT, 2019). However, working towards increasing CRCS continues to be a goal for the NCCR and they revealed a new campaign for 2019 that is titled "80% in Every Community" that began on March 7th, 2019. The NCCRT decided on this campaign as there is still CRCS rate disparities in communities that consist of rural populations, people ages 50-54 especially men, and racial/ethnic groups (NDCRC, 2019). The survey that was used in this practice improvement project did not specify what age the individual was, however, asked if they fell within the ages of

50 to 75 years old. Age should be specified in future projects to better understand if the disparity of people not being screened in the age category of 50-54 years old and 50-64 years old is occurring in this rural, ND town or in other comparable locations/project sites. Including the specific age on the survey instead of asking if they fall within the ages of 50-75 years old could have better depicted if there was a gap of screening between the ages of 50-54 and 50-64 years or age as the CDC (2019) has identified. The CDC states that not having Medicare coverage for the 50-64 years old could be a factor as to why there is a lower amount of this age group being screened (59%) compared to the age group 65-75 (73.8%) (CDC, 2018b). Another limitation could have been not incorporating a previously studied evidenced-based survey in order to better assess participant barriers and perceptions.

Offering screening throughout community events beyond influenza vaccinations could potentially increase the knowledge and awareness of CRC. Since, many participants identified that they would like to receive information about their health through their clinic or health care provider, primary care health organizations could also hold special events with educational information about CRCS and awareness.

#### **Implications for Advanced Practice Nursing**

Implications for advanced practice nursing were identified after the completion of this practice improvement project. The first implication for advanced practice nursing was the collaboration efforts between the Public Health Department and Primary Health Clinic involved in this project. The co-investigator acted as a liaison between the two organizations, which was significant in this project for development and implementation of this practice improvement project. Participating in the "80% in Every Community Initiative" could help target the unscreened population such as males, age groups between 50-54 and 50-65 years old. The "80%

in Every Community Initiative" (NCRT, 2019) states that healthcare providers should be vigilant to identify signs and symptoms of CRC along with obtaining a family history of CRC for all patients especially those who fall under the USPSTF (2016) recommendations of CRCS for adults between the ages of 50-75 years old as there has been an increase of people below the age of 50 being diagnosed with CRC. Collaborating throughout the community can help promote healthy behaviors and prevent disease occurring that could ultimately lead to improved patient outcomes, such as preventing CRC or finding CRC in early stages through CRCS.

Another implication for advanced practice nursing is to use the survey again that was developed in this practice improvement project to further refine the survey for future validation. Understanding client's health behaviors could help clinicians tailor a health plan for them. Understanding community trends regarding CRCS could help develop future goals to work towards that did impact the overall community's health care needs, ultimately leading to healthier lives and communities through health promotion and disease prevention. Having clerical and nursing staff, or at least some person in this role, to discuss the project with potential participants appears to yield more results versus having a poster alone to describe the project.

A final implication for advanced practice nursing is for future efforts to build on the literature of body that supports FluFIT Clinics, such as this project, that aides in identifying information to help fill the gap in disparities in CRCS. While this project had a small number of participants, there were three participants who would have accepted a FIT if all primary care health organizations were involved with this project, which, in turn, would have slightly increased CRCS rates in this community. Future efforts to collaborate with all applicable organizations within a community could potentially yield more influential results at FluFIT Clinics.

#### **Application to DNP Roles**

Completing this practice improvement project has contributed to how DNP prepared practitioners can make valuable contributions as effective leaders in a community, acting as the liaison between the Public Health Clinic and Primary Care Clinic to implement a practice improvement project. Collaborating with Primary Care and Public Health is a cornerstone of decreasing health care disparities throughout a community. DNP practitioners are prepared to be such leaders as the DNP Essentials consist of a framework that prepares the DNP to be a leader, foster interprofessional collaboration, and exercise leadership skills (Moran, 2017).

The AACN DNP Essential VI describes how DNPs are prepared to act as leaders that facilitate interdisciplinary collaboration that can improve both patient and population outcomes (American Association of Colleges of Nursing [AACN], 2006). Working together towards a common goal to increase the health and well-being of a community by increasing the CRCS rates, empowers DNPs to become the leaders they were trained to be. The DNP Essential II goes along with increasing the leadership role, as DNPs are educated in organization and systems leadership for quality improvement and systems thinking which improves client and health care outcomes (Moran, 2017).

The DNP prepared practitioner demonstrates the ability to improve patient outcomes by having the highest degree of nursing practice (Moran, 2017). Having the highest degree allows the DNP to apply evidenced-based research into practice on a timely basis (AACN, 2006). Thus, DNPs make exceptional program evaluators whom can implement a practice improvement project and evaluate the interventions which in turn can be used to educate others and improve patient outcomes while using EBP.

The DNP prepared practitioner can impact the provider shortage at the scholarly level by translating research into practice and contributing to the body of knowledge in the area of interest and influence. Improved practice and mentoring through the demonstration of scholarly leadership can improve practice for nurse practitioners and aide in better educating students as well. The majority of practitioners prefer to work in primary care and in a rural setting as indicated by the number of NP's who work in rural areas has steadily increased from 17.6% in 2008 to 25.2% in 2016 (put reference here and end the sentence). This finding shows that educating nurses to become practitioners is increasing access to care in rural areas, thus merging the gap between access to care and provider shortage (Barnes, Richards, McHugh, & Martsolf, 2018). The hope of the co-investigator is that more nurses are inspired to obtain a DNP degree to help merge the gap of the health care provider and educator shortage to ultimately increase patient and population outcomes.

#### Conclusion

The practice improvement project involved the development and implementation of a FluFIT project at both a Primary Care Clinic and a Public Health Department to help increase CRCS rates and awareness in a rural, ND town. CRC affects both men and women equally. There is a gap between the screened and the unscreened population that needs to be filled to increase screening rates and decrease CRC rates. The FIT test appears to be beneficial at detecting CRC by having improved sensitivity over the gFOBT testing, has a higher specificity than the FIT-DNA (Cologuard) and has a lower false positive rate than the FIT-DNA test (Imperiale et al., 2014; USPSTF, 2016). The FIT appears to be the most cost-effective CRCS test (Wong et al., 2015). Colorectal cancer is the third leading cancer in America and is the second cause of all cancer related deaths (CDC, 2017a). Colorectal cancer is preventable, detectable, and treatable, especially when caught in the early stages (NDCRC, 2017). Currently only one in three adults aged 50-75 years old are screened for colorectal cancer (CDC, 2017a). Approximately 35% of the population of North Dakota whose age is between 50-75 years and who meet the criteria are participating in colorectal screening (NDCRC, 2017). North Dakota needs to screen 68,000 people to achieve the NCCR 80% initiative (NCCR, 2017). According to the NDCRC, colorectal deaths in ND could be reduced by 60% if everybody between the ages of 50-75 years old had regular colorectal screenings (NDCRC, 2017). Implementing CRCS and educational information during influenza vaccinations could successfully increase the rates of adults who are screened for CRC (AHRQ, 2014; NIH, 2017; Potter et al., 2013; Verma et al., 2015; Weiner et al., 2017).

The goal of this practice improvement project was to increase CRCS awareness and screening rates. Even though the goal of increasing CRCS rates was not met, the goal of increasing awareness was met by providing educational brochures regarding CRC and CRCS options to members of the community. Collaborating as a community is key in providing a sustainable solution to increase CRCS rates in a community. This practice improvement project can augment the literature for future practice improvement projects to continue to help merge the gap of the unscreened population to the screened population for CRC, leading to improved health outcomes.

#### REFERENCES

- Agency for Healthcare Research and Quality. (2014). *Primary Care Clinic simultaneously offers influenza shot and home testing kit to eligible patients during influenza season, boosting colorectal cancer screening rate*. Retrieved from https://innovations.ahrq.gov/profiles/primary-care-Clinic-simultaneously-offersinfluenza-shot-and-home-testing-kit-eligible
- Allison, J. E., Fraser, C. G., Halloran, S. P., & Young, G. P. (2014). Population screening for colorectal cancer means getting FIT: The past, present, and future of colorectal screening using the fecal immunochemical test for hemoglobin (FIT). *Gut and Liver*, 8(2), 117-130. https://doi.org/10.5009gnl.2014.8.2.117
- American Association of Colleges of Nursing. (2006). *The essentials of doctoral education for advanced nursing practice*. Retrieved from

https://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf

- American Cancer Society. (2017a). *Colorectal Cancer Screening Tests*. Retrieved from https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screeningtests-used.html
- American Cancer Society. (2017b). *Key statistics for colorectal cancer*. Retrieved from https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html
- American Society for Gastrointestinal Endoscopy. (2017). Understanding bowel preparation: What bowel preparation steps are involved before the colonoscopy? Retrieved from https://www.asge.org/home/for-patients/patient-information/understanding-bowelpreparation

- Barnes, H., Richards, M. R., McHugh, M. D., & Martsolf, G. (2018). Rural and nonrural primary care physician practices increasingly rely on nurse practitioners. *Health Affairs*, 37(6), 908-914. https://doi.org/10.1377/hlthaff.2017.1158
- Cabebe, E. C., & Espat, J. N. (2017). Colorectal cancer guidelines. Retrieved from http://emedicine.medscape.com/article/2500006-overview
- Cagir, B., & Espat, J. (2017). Rectal cancer: Pathophysiology in *Emedicine*. Retrieved from http://emedicine.medscape.com/article/281237-overview#a5
- Cancer Treatment Centers of America. (2017). *Colorectal cancer types*. Retrieved from http://www.cancercenter.com/colorectal-cancer/types/
- Centers for disease control and prevention. (2017a). *Basic information about colorectal cancer*. Retrieved from https://www.cdc.gov/cancer/colorectal/basic\_info/index.htm
- Center for Disease Control and Prevention. (2017b). *Colorectal Cancer Statistics*. Retrieved from https://www.cdc.gov/cancer/colorectal/statistics/index.htm
- Centers of Disease Control and Prevention. (2018). *Expected new cancer cases and deaths in 2020*. Retrieved from

https://www.cdc.gov/cancer/dcpc/research/articles/cancer\_2020.htm

Darrow, J. (2014). Capsule endoscopy instead of colonoscopy? The FDA approves pillcam colon. The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. Retrieved from http://blog.petrieflom.law.harvard.edu/2014/03/04/capsule-endoscopy-instead-ofcolonoscopy-the-fda-approves-the-pillcam-colon/

Dang, D., Mazurek, B., Fineout-Overholt, E., Ciliska, D., DiCenso, A., Cullen, L., ... Stevens, K.R. (2015). Models to guide implementation and sustainability of evidence-based practice.

In R. Bushing (Ed.), *Evidence-based practice in nursing and healthcare: A guide to best practice* (3rd Ed.) (pp. 274-315). Philadelphia, PA: Wolters Kluwer Health.

- De Vincentis, F., Cesaro, P., Hassan, C., Riccioni, M. E., Grazioli, L. M., Bolivar, S., ... Costamagna, G. (2012). Accuracy and safety of second-generation PillCam Colon capsule for colorectal polyp detection. *Therapeutic Advances in Gastroenterology*, 5(3), 173-178. https://doi.org/10.1177/1756283X12438054
- Department of Family and Community Medicine University of California, San Francisco. (UCSF, 2016). FluFIT. Retrieved from http://flufit.org/staff-traning/
- Exact Sciences. (2017). *Cologuard*. Retrieved from http://www.cologuardtest.com/what-iscologuard
- Fain, J. A. (2015). Applying appropriate theories and conceptual models (4<sup>th</sup> Ed.). In E. Gerhart (Eds.), *Reading, understanding, and applying nursing research* (pp. 89-102).
  Philadelphia, PA: F.A. Davis Company.
- Frazier, A. B. (2004). Colorectal cancer screening: A non-invasive approach. Retrieved fromProQuest Dissertations & Thesis Global. 1436613
- Gogtay, N., & Thatte, U. (2017). Statistical evaluation of diagnostic tests (part 1): Sensitivity, specificity, positive and negative predictive values. *Journal of the Association of Physicians of India*, 65(6), 80-84. Retrieved from http://www.japi.org/june\_2017/11\_sfr\_statistical\_evaluatio.pdf
- Grady, W. M., & Markowitz, S. D. (2014). The molecular pathogenesis of colorectal cancer and its potential application to colorectal screening. *Digestive Diseases and Sciences*, 60(3), 762-772. https://doi.org/10.1007/s10620-014-3444-4

Guillaume, E., Dejardin, O., Bouvier, V., De Mil, R., Berchi, C., Pornet, C., ... Launoy, G. (2017). Patient navigation to reduce social inequalities in colorectal cancer screening participation: A cluster randomized controlled trial. *Preventive Medicine*, *103*, 76-83. https://doi.org/10.1016/j.ypmed.2017.08.012

Gupta, S., Sussman, D. A., Doubeni, C. A., Anderson, D. S., Day, L., Deshpande, A. R., ... Martinez, M. E. (2014). Challenges and possible solutions to colorectal cancer screening for underserved. *Journal of National Cancer Institute*, 106(4). https://doi.org/10.1093/jnci/dju032

- Imperiale, T. F., Ransohoff, D. F., Itzkowitz, S. H., Levin, T. R., & Lavin, P. (2014). Multitarget stool DNA testing for colorectal-cancer screening. *The New England Journal of Medicine*, 370(14), 1287-1297. https://doi.org/10.1056/NEJMoa1311194
- Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. Worldviews on Evidence-Based Nursing, 14(3), 175-182. https://doi.org/10.1111/wvn.12223
- Kim, B., Lairson, D., Chung, T., Kim, J., & Shokar, N. K. (2017). Budget impact analysis of against colorectal cancer in our neighborhoods (ACCION): A successful communitybased colorectal cancer screening program for a medically underserved minority population. *Value in Health*, 20(6), 809-818. https://doi.org/10.1016/j.jval.2016.11.025
- Kirkoon, B., Berstad, P., Botteri, E., El-Safadi, B., Hoff, G., De Lange, T., & Bernklev, T. (2016, November 21). Psychological effects of colorectal screening: Participants vs individuals not invited. *World Journal of Gastroenterology*, 22(43), 9631-9641. https://doi.org/10.3748/wjg.v22.i43.9631

- Mazureck Melnyk, B., & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing & healthcare: A guide to best practice* (3rd d.). Philadelphia, PA: Wolters Kluwer Health.
- McKenzie, J., Talukder, A., & Alco, D. (2017). Colon Cancer. In F. Domino, R. A. Baldor, J.
  Golding, & M. B. Stephens (Eds.), *The five-minute Clinical consult 2018* (26th ed., pp. 202-203). Philadelphia, PA: Wolters Kluwer.
- Moran, K. (2017). Setting the stage for the doctor of nursing practice scholarly project. In R.
  Burson & D. Conrad (Eds.), *The doctor of nursing practice scholarly project* (2nd ed., pp. 3-14). Burlington, MA: Jones & Bartlett Learning.
- National Cancer Institute. (2017). FluFIT and Flu-FOBT program. Retrieved from https://rtips.cancer.gov/rtips/programDetails.do?programId=1084580
- National Colorectal Cancer Roundtable. (2017). 80% by 2018: Recommended messaging to reach the unscreened. Retrieved from http://nccrt.org/wp-content/uploads/CRC-Communications-Guidebook-20170307.pdf
- North Dakota Comprehensive Cancer Control Program. (2017). North Dakota Colorectal Cancer Roundtable. *North Dakota Department of Health*. Retrieved from http://www.ndhealth.gov/compcancer/cancer-programs-and-projects/80-by-2018/
- North Dakota Comprehensive Cancer Control Program. (2019). North Dakota Colorectal Cancer Roundtable. *North Dakota Department of Health*. Retrieved from http://www.ndhealth.gov/compcancer/cancer-programs-and-projects/80-by-2018/
- Pender, N., Murdaugh, C., & Parsons, M. A. (2015). Individual models to promote health behavior. In E. Sullivan (Ed.), *Health promotion in nursing practice* (7th ed. pp. 26-53).
  Reprinted by permission of Pearson Education, Inc., New York, New York.

- Potter, M. B., Ackerson, L. M., Gomez, V., Walsh, J. M., Green, L. W., Levin, T. R., & Somkin, C. P. (2013). Effectiveness and reach of the FluFIT program in an integrated health care system: A multisite randomized trial. *American Journal of Public Health*, *103*(6), 1128-1133. https://doi.org/10.2105/AJPH.2012.300998
- Rowe, N. (2013). What is the evidence that poster presentations are effective in promoting knowledge transfer? A state of the art review. *Health Information and Libraries Journal*, 30(1), 4-12. https://doi.org/10.1111/hir.12015
- Singal, A. G., Gupta, S., Skinner, C. S., Ahn, C., Santini, N. O., Agrawal, D., ... Halm, E. A. (2017). Effect of colonoscopy outreach vs fecal immunochemical test outreach on colorectal cancer screening completion: A randomized Clinical trial. *JAMA*, *318*(9), 806-815. https://doi.org/10.1001/jama.2017.11389
- Tangka, F. K., Subramanian, S., Beebe, M. C., Hoover, S., Royalty, J., & Seeff, L. C. (2013). Clinical costs of colorectal cancer screening in 5 federally funded demonstration programs. *Cancer*, *119*(S15), 2836-2869. https://doi.org/10.1002/cncr.28154
- United States Census Bureau. (2015). *American fact finder*. Retrieved from https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk
- United States Preventive Services Task Force. (2016). Screening for colorectal cancer US preventive services task force recommendation statement. *JAMA*, *315*(23), 2564-2575. https://doi.org/10.1001/jama.2016.5989
- Verma, M., Sarfaty, M., Brooks, D., & Wender, R. C. (2015). Population-based programs for increasing colorectal cancer screening in the United States. *CA: A Cancer Journal for Clinicians*, 65(6), 496-510. https://doi.org/10.3322/caac.21295

- Weiner, B. J., Rohweder, C. L., Scott, J. E., Teal, R., Slade, A., Deal, A. M., ... Wolf, M. (2017).
  Using practice facilitation to increase rates of colorectal cancer screening in community health centers, north carolina, 2012-2013: Feasibility, facilitators, and barriers. *Preventing Chronic Disease*, *14*, E66. https://doi.org/10.5888/pcd14.160454
- Wong, M. C., Ching, J. Y., Chan, V. C., & Sung, J. J. (2015). The comparative cost-effectiveness of colorectal cancer screening using faecal immunochemical test vs. colonoscopy. *Science Reports*, 5(1), 13568. https://doi.org/10.1038/srep13568
- Wong, R. K., Wong, M. L., Chan, Y. H., Feng, Z., Wai, C. T., & Yeoh, K. G. (2013). Gender differences in predictors of colorectal cancer screening uptake: a national study based on the health belief model. *BMC Public Health*, *13*(1), 677. https://doi.org/ 10.11861471-2458-13-677
- World Health Organization. (2017). *Health promotion*. Retrieved from https://www.who.int/topics/health\_promotion/en/

#### **APPENDIX A. EXECUTIVE SUMMARY**

#### **Project Summary**

Colorectal cancer (CRC) is the second leading cause of cancer related deaths in the nation that is highly preventable, detectable, and treatable when caught early through various colorectal cancer screening (CRCS) methods (CDC, 2017). However, the national CRCS rates remain low despite the recommendations to screen adults, ages 50-75 years (USPSTF, 2016). The purpose of this project was to increase public awareness through education at FluFIT sites and increase screening rates with possible FIT to participants meeting screening criteria during the 2017-2018 influenza seasons (NCCR, 2017).

#### Background

While 64% of the population, ages 50-75 years, in North Dakota (ND) are participating in colorectal cancer screening (CRCS), there is a nationwide challenge to increase CRCS to 80% by 2018 (NCCR, 2017; NDCRC, 2017). The North Dakota Colorectal Cancer Roundtable (NDCCRT) accepted the challenge and recommended four strategies to increase CRCS; this project focused on the implementing FluFIT (fecal immunochemical test) Clinics strategy. Multiple researchers have determined that implementing CRCS on a population-based approach throughout a community has been beneficial to increase rates of CRCS (AHRQ, 2014; NIH, 2017; Potter et al., 2013; Verma et al., 2015; Weiner et al., 2017). The local, county Public Health Department collaborated with one of the primary care clinics to each host the FluFIT sites.

#### Process

Education was provided to staff involved from both entities including nurses and clerical staff present at FluFIT sites and health care providers from the Primary Care Clinic to enter

orders for FIT screenings and follow-up on results. Potential participants, ages 50-75 years, coming to FluFIT sites for influenza vaccination were provided informational brochures and asked to fill out a survey regarding knowledge and factors impacting screening decisions for CRC in a rural, ND town to increase public awareness and aide future planning for improved screening processes through Public Health. Implementation took place during the 2017-2018 influenza seasons.

#### **Findings and Conclusions**

There were 31 total participants. Only five of the participants met criteria for CRCS with FIT testing between all sites, though none were able to complete screening through the FluFIT sites. The number of distributed informational brochures totaled 347. Despite limited participation and limitations in design, the results educated more of the community and provided Public Health with information on CRCS knowledge and beliefs to impact further research and identify barriers, while also supporting current literature that indicates there are unscreened individuals in ND. This project can assist future projects to merge the gap of the unscreened CRC population, leading to optimal health outcomes. Results from the project are presented in the graphs below.



Figure A1. Survey Results



Figure A2. Benefits and Barriers to CRCS



Figure A3. Start or Continue CRCS

#### **Recommendations for Further Action**

To improve CRCS rates and awareness for those who meet the recommendations for screening:

- Collaborate will all suitable entities throughout the community to implement FluFIT clinics.
- Begin implementation at the beginning of the influenza season.
- Distribute the information in the same manner each year.
- Incorporate a previously studied evidenced-based survey to better assess participant barriers and perceptions.
- Offering screening throughout community events beyond influenza vaccinations could potentially increase the knowledge and awareness of CRC.
- Build on the literature of body that supports FluFIT Clinics, such as this project, that aides in identifying information to help fill the gap in disparities in CRCS, leading to improved health outcomes.



#### **APPENDIX B. HEALTH PROMOTION MODEL (REVISED)**

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#### APPENDIX C. PERMISSION TO USE NOLA PENDER'S HEALTH PROMOTION

#### MODEL



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Apr 9, 2019

PE Ref # 208553

LAURA BOND c/o NDSU 2007 4th St. NE Jamestown, ND 58401

Dear Laura

You have our permission to include content from our text, *HEALTH PROMOTION IN NURSING PRACTICE*, *7th Ed. by PENDER*, *NOLA J.; MURDAUGH*, *CAROLYN L.; PARSONS*, *MARY ANN*, in your dissertation at North Dakota State University.

Content to be included is: Figure 2-3 "The Health Promotion Model (Revised)" on page 35

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Sincerely, Allison Bulpitt, Permissions Analyst

#### APPENDIX D. THE IOWA MODEL REVISED: EVIDENCE-BASED PRACTICE TO

#### PROMOTE EXCELLENCE IN HEALTH CARE



### APPENDIX E. COLORECTAL CANCER AWARENESS BROCHURE





Get Tested for Colon Cancer



They know how to prevent colon cancer – and you can, too.

# Take a look inside.



If you're 50 or older, you need to get tested for colon cancer.

# It's one cancer that can actually be prevented!

## Colon cancer: Should you be concerned?

If you're 50 or older, the answer is yes.

If you're 50 or older, you need to think about colon cancer. Most colon cancers occur in men and women who are 50 or older.

# But no one in your family has had colon cancer?

Most people who get colon cancer have no family history of the disease. And you can have colon cancer and not even know it. If you have a parent, brother, sister, or child who has had colon cancer, then testing is even more important for you. In fact, you may need to start testing before you're 50.



## Get tested.

You have the power to help stop colon cancer before it starts. Colon cancer begins with a growth (called a polyp) that's not yet cancer. Testing can help your health care provider tell whether there's a problem, and some tests can find polyps before they become cancer. Most people who have polyps removed never get colon cancer. If colon cancer is found, you have a good chance of beating it with treatment if it's found early (when it's small and has not spread). And testing can help find it early.

We believe that **preventing** colon cancer (and not just finding it early) should be a major reason for getting tested. When polyps are found and removed, it can keep some people from getting colon cancer. Tests that have the best chance of finding both polyps and cancer should be your first choice if these tests are available and you're willing to have them.


Talk to your health care provider about getting tested for colon cancer.

# Ask for the test.

As you get older, you have more health concerns. Your health care provider has a lot to talk to you about. If your provider doesn't mention getting tested for colon cancer, don't be afraid to ask about it. There's more than one way to get tested, so you and your provider should choose the test that's best for you.

You owe it to yourself and the people who love you to take care of yourself.

# What is colon cancer?

Cancer of the colon or rectum is called colon cancer.

# What do the colon and rectum do?

The colon and rectum help the body digest food. They hold waste until it passes out of the body.



The colon is also called the large intestine.



# What are the tests for finding polyps and colon cancer?

# Flexible sigmoidoscopy

A narrow, lighted tube is used to look inside your rectum and lower part of the colon. The doctor will be looking for cancer or polyps that could turn into cancer. If they see something, they can take a piece of it and test it for cancer. This test allows the doctor to look at only the lower part of the colon. If any growths or polyps are found, a colonoscopy will need to be done.

## Colonoscopy

A narrow, lighted tube is used to look at the inside of the rectum and the entire colon. The doctor will be looking for cancer or polyps that could turn into cancer. If they see any polyps or growths, they can remove it or take a piece to test it for cancer. Patients are usually given drugs to make them sleep during a colonoscopy.

## Double-contrast barium enema

After a special enema is given, x-rays are taken of your rectum and colon. The barium in the enema coats the inside of the rectum and colon. The x-rays can then show any growths or polyps. If a change is seen, a colonoscopy will need to be done so the doctor can remove it or take a piece to test for cancer.

## CT colonography

With this test, air is pumped into your colon. Then a special type of x-ray called a CT scan is done. The test can be done quickly and with no sedation. If a polyp or growth is found, a colonoscopy must be done to remove it or take a piece to test for cancer.

Remember: These tests offer the best chance of finding both polyps and cancer, and they're preferred if they're available and you're willing to have them.

# What are the tests for finding colon cancer?

# Guaiac-based fecal occult blood test (gFOBT)?

Your health care provider will give you a test kit to take home. You will need to smear a small amount of your poop on a card. You'll do this for 3 bowel movements. The cards are returned to your provider's office or a lab to be tested. Testing will tell your provider if there is blood in your poop. If blood is present, a colonoscopy will need to be done to look for the cause of the blood. This test can help find some cancers in the colon, but it can also miss some.

## Fecal immunochemical test (FIT)

Your health care provider will give you a test kit to take home. You will put a small amount of your poop on a card. The kit will explain how to do this. You may have to do this on 2 or 3 cards, depending on the kind of test kit you're given. The cards are returned to your provider's office or a lab to be tested. Testing will tell your provider if there is blood in your poop. If blood is found, a colonoscopy will need to be done to



look for the cause of the blood. This test can help find some colon cancers, but it can also miss some.

# Stool DNA test (sDNA test)

This test checks your poop for cancer cells. Your health care provider will give you a test kit to take home. You will collect a sample of your poop and return it to a lab to be tested. This test will find some colon cancers, but it can also miss some. If the test finds cells that may be cancer a colonoscopy will need to be done.

# How do I prepare for these tests?

For the sigmoidoscopy, colonoscopy, double-contrast barium enema, and the CT colonography, your colon will need to be cleaned out as much as possible. You may need to have only clear liquids and no food for some time before the test. You'll take a strong laxative the day before the test and may need to give yourself an enema the morning of the test.

No advance preparation is needed for the stool tests. You'll have to follow the instructions of the kit and will need to return the kits to either your provider or a lab for testing.

# How do I know if I need any of these tests?

- If you are 50 or older, you need to be tested for colon cancer.
- If someone in your family has had colon cancer, you might need to be tested before you're 50. Talk to your provider about your family history.
- If you have certain medical conditions, you might need to be tested for colon cancer earlier than age 50. Talk to your provider about this.

# Which tests are best for me?

When polyps are found and removed, it can help keep some people from getting colon cancer. Tests that have the best chance of finding both polyps and cancer should be your first choice when possible. Talk with your health care provider to find out which tests you can get, and then decide which test you want to have.

## The American Cancer Society recommends that starting at age 50 you have one of these tests:

## Tests that find polyps and cancer

Flexible sigmoidoscopy\* every 5 years, or Colonoscopy every 10 years, or Double-contrast barium enema\* every 5 years, or CT colonography (virtual colonoscopy)\* every 5 years

## Tests that find cancer

Yearly guaiac-based fecal occult blood test (gFOBT),\* or Yearly fecal immunochemical test (FIT),\* or Stool DNA test (sDNA)\* every 3 years

\*If any of these tests are abnormal, you will need to have a colonoscopy.

# How can I find out more about colon cancer?

Asking about colon cancer testing isn't always easy. The American Cancer Society can help. Call us anytime, day or night, at 1-800-227-2345. We can tell you more about the tests, help you talk to your health care provider, or listen to your concerns.

Together, we can help stop colon cancer before it starts. Talk to your provider about getting tested for colon cancer. Written January 2016





cancer.org | 1.800.227.2345 1.866.228.4327 TTY



©2006, American Cancer Society, Inc. No.243900-Rev. 1/16 Models used for illustrative purposes only.

## APPENDIX F. PERMISSION TO USE EDUCATIONAL BROCHURE

Permission to use American Cancer Society Colorectal Cancer Awareness Brochure

Shannon Bacon–American Cancer Society

Thursday 8/31/2017 3:46 PM

To: Laura Bond

Thank you, Laura! I found about 500 brochures that I did drop in the mail tomorrow for you guys. Here is what the brochures look like:<u>https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/they-know-how-to-prevent-colon-cancer-handout.pdf</u>. Let me know if you need me to order more than this and ship directly to you.

Here are a few other resources you may find helpful:

- CRCS infographic: <u>https://www.cancer.org/content/dam/cancer-org/online-</u> documents/en/pdf/infographics/colorectal-cancer-catching-it-early-infographic-print.pdf
- <u>www.flufit.org</u>
  - Includes staff training tips, program materials such as eligibility algorithm, poster templates for advertising, sample log sheet and sample tracking sheet, sample postcard reminders, phone reminders script, etc.

Thanks, Laura. Please let me know if there's anything else I can help with.

-Shannon

Shannon **Bacon, MSW** | Health Systems Manager, State-Based North Region | American Cancer Society, Inc.

## APPENDIX H. COLORECTAL CANCER AWARENESS SURVEY

- 1. Are you in between the ages of 50 to 75? Yes No (If no end of survey, Thank you!)
- 2. Please circle if you are: Male or Female
- Please circle which ethnicity best describes you:
   Caucasian Hispanic or Latino Black or African America American Indian Asian/Pacific Islander Other
- 4. Do you have private health insurance? Yes or No
- 5. Do you have Medicare? Yes or No
- 6. Have you ever had CRCS done? Yes or No
  - If yes, list what year you had it done\_\_\_\_\_\_
  - And circle which test you had done

     Stool testing (at home kits)
     Procedure: Colonoscopy, sigmoidoscopy or CT scan
- 7. Has your Primary Care provider talked to you about CRCS? Yes or No
- Did you know that you can complete CRCS in the privacy of your own home? Yes or No
- 9. Have you, a family member, or a friend ever been diagnosed with colorectal cancer?

Yes or No

- 10. Circle any or all benefits that CRCS offers you.
  - Prevent colorectal cancer
  - Detect colorectal cancer
  - Treat colorectal cancer early
  - Peace of mind
  - Not sure

11. Circle any or all the following that might keep you from screening for colorectal cancer:

- Costs too much to be screened
- I cannot get to a place to be screened
- I am not sure of what screening options there are

• I do not want to talk about colorectal screening

12. How do you consider your overall health?

- Very Healthy
- Healthy
- Somewhat Healthy
- Not Healthy at all

13. How do you like to get information about your health? (please circle your top choice)

- Clinic/Provider Office
- At your work place
- In the community (community center, Public Health office)
- Family and Friends
- Facebook
- Newspaper
- Radio
- All the above

14. How likely are you to start or continue CRCS?

- Very Likely
- Likely
- Somewhat likely
- Not likely at all

15. Please describe why or why not? (regarding the question above)

## APPENDIX I. FLUFIT STAFF TRAINING INFORMATION AND PERMISSION TO

#### USE





### STAFF TRAINING

Setting up a FLU-FIT or FLU-FOBT Program requires training for the staff who will be interacting directly with your patients. The training that you provide will depend on the way you organize your program and the type of staff that are involved. For example, if your clinic site is already experienced in providing FIT and FOBT kits to patients without a doctor's order, your team may not need very much training at all. However, if your team has never provided FIT or FOBT in the past, more training will be needed.

#### The 5 key elements to include in your training should include:

#### 1. Information about the importance of both flu shots and colorectal cancer screening.

Your staff should know a few facts about flu shots and colorectal cancer screening:

#### Facts about Flu and Flu Shots:

- · Flu is often mild, but can be a very serious illness
- Depending on the season, the CDC estimates that between 3,000 and 49,000 Americans die of complications from the flu each year
- · Flu shots are one of the best tools we have to prevent people from getting flu
- Flu shots are safe when provided as directed
- Flu shots do not cause the flu
- · Flu shots are recommended for everyone over the age of 6 months.

More information about flu and flu shots can be found on the CDC's seasonal flu website: http://www.cdc.gov/flu/index.htm

#### Facts about colorectal cancer and screening:

- 2nd leading cause of cancer in the United States
- More than 50,000 Americans die of colorectal cancer each year
- Colorectal cancer is often preventable with screening
- Early detection and treatment saves lives
- There are more than 1 million colorectal cancer survivors in the United States
- Colorectal cancer screening is recommended between the ages of 50 and 75

More information about colorectal cancer and colorectal cancer screening can be found on the USPSTF website: http://www.uspreventiveservicestaskforce.org/uspstf08/colocancer/colors.htm





#### 2. Information about how to organize your workflow efficiently.

In most clinical settings, it is best to plan to offer FIT or FOBT either immediately before or during administration of flu shots. It is also important to give consideration to how your space is organized so that it will be comfortable for patients and staff.

If you have a busy, high volume setting, you will want to have someone dedicated to managing the flu shot line to keep things running smoothly. You may also want to set up a separate station for FIT/ FOBT several feet in front of the station where flu shots are being offered.

If you are in an outpatient clinic that is providing the FLU-FIT or FLU-FOBT Program during primary care visits, or in a lower volume setting with limited space, you will likely want to provide FIT/FOBT and flu shots together at the same clinic station.

Make sure to select all of your patient education materials in advance and have your work stations well stocked with FIT/FOBT kits and flu shots so that your team is well prepared for success.

#### Assessing eligibility for flu shots and for FIT or FOBT without waiting for a doctor's order.

The CDC has developed detailed free training programs for health professionals and clinic staff who provide flu shots. These can be accessed at: http://www.cdc.gov/flu/index.htm

Patients are eligible for colorectal cancer screening with FIT or FOBT if they are between the ages of 50 and 75 and also have had:

- No FIT or FOBT in the last year
- No colonoscopy in the last 10 years

Patients with other colorectal cancer screening tests, such as flexible sigmoidoscopy or barium enema usually can still benefit from annual FIT/FOBT. Patients with an abnormal FIT/FOBT should be referred for colonoscopy to check for polyps or cancer before considering having FIT/FOBT repeated.

Eligibility for FIT/FOBT may determined by reviewing clinic charts or your electronic health record. One time-saving approach for clinics with electronic health records is to print out a list of patients who are due for FIT/FOBT at the beginning of the flu shot season, and use it as a quick reference to select appropriate patients for FIT/FOBT as they come in for their flu shots.

When clinic charts or electronic health records are not available, the clinic staff can as the patient about prior FIT/FOBT and colonoscopy procedures. As long as the patient is reasonably certain that he or she has not completed a recent FIT or FOBT kit and that they have not had a colonoscopy for the last several years, it is reasonable to offer a FIT or FOBT kit with their flu shot.





# 4. Talking to patients about FIT or FOBT and how to complete the test.

Colorectal cancer screening is a serious topic, but patients are usually receptive to hearing about it, especially when the conversation is kept simple and light. What you say to patients will depend on how your FLU-FIT or FLU-FOBT Program is set up and what type of kit you provide to patients. Effective talking points may include phrases like this:

- · We have something extra to offer you today!
- · It looks like you are due for a home colon test
- · Colon cancer screening can save lives
- · Just like a flu shot, all our doctors and nurses recommend home colon tests
- · It's very easy -- you can do it in the privacy of your home and mail it in
- · We'll make sure the results get to your doctor

Patients who accept the kit should be given additional written material and instructions. If the patient is unfamiliar with FIT or FOBT, it is can be useful to take a moment to show the patient the kit and offer simple instructions with a visual aid or a brief instructional video. We have provided sample patient education materials in our PROGRAM MATERIALS Page

# 5. Information about how to record their work and provide follow-up of FIT or FOBT kits provided to patients.

For tracking purposes, you will want to keep a record of which patients were given FIT or FOBT. This information can be recorded on a log sheet where flu shots are also recorded. This list can be useful to determine test return rates and to provide reminders to patients who have not yet returned kits that have been dispensed. The log sheet can be used to gather information to track and arrange follow-up of abnormal test results. Examples of a log sheet and abnormal test result tracking form is listed in PROGRAM MATERIALS.

Hello Dr. Potter,

I am a Doctor of Nursing Practice student at the North Dakota State University. I am doing my dissertation on increasing colorectal cancer screening rates in a rural community and was wondering if I can incorporate the FluFIT program and staff training information into my project? Please, let me know if I have permission or not to use these materials.

Sincerely,

Laura Bond, DNP-S NDSU

## E-mail response from Dr.Potter:

Yes, but please acknowledge their source and good luck! Best - Mike Potter

## APPENDIX J. PERMISSION TO USE THE IOWA MODEL

Permission to Use the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in

Health Care

Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qualtircs-survey.com>

Saturday 9/9/2017 2:09 PM

To: Laura Bond

You have permission, as requested today, to review and/or reproduce The Iowa Model Revised:

Evidence-Based Practice to Promote Excellence in Health Care. Click the link below to open.

The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

Copyright is retained by University of Iowa Hospitals and Clinics. **Permission is not granted for placing on the internet.** 

**Citation:** Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing*, 14(3), 175-182. doi:10.1111/wvn.12223

In written material, please add the following statement: Used/reprinted with permission from the University of Iowa Hospitals and Clinics, copyright 2015. For permission to use or reproduce, please contact the University of Iowa Hospitals and Clinics at 319-384-9098.

Please contact <u>UIHCNursingResearchandEBP@uiowa.edu</u> or 319-384-9098 with questions.

### APPENDIX K. POSTER FOR PUBLIC HEALTH CLINIC



#### APPENDIX L. ORAL INFORMED CONSENT SCRIPT

Hello, we are participating in a project that is led by an NDSU graduate nursing student who is researching how to increase the number of adults being screened for colorectal cancer in our community. The recommended age to start CRCS is at age 50 and through the age of 75, as this is the most at-risk time to develop colorectal cancer. Colorectal cancer is the second leading cause of cancer related deaths in the United States that can be prevented, detected, and treated when caught early. Since you fall within the age group, would you like to receive more information about colorectal cancer and screening tools during your visit?

If you would like more information, we have an educational brochure and short survey to complete which did let us know if you are able to receive a CRCS kit if you are deciding to do this or your reasons for choosing not to be screened. The results for the survey did help identify what is needed to improve CRCS rates in our community. All surveys were anonymous and by completing the survey you give consent to participate in the research for this project. Your time and interest in this project are appreciated!

## APPENDIX M. SURVEY COVER LETTER

## Hello!

My name is Laura Bond and I am a graduate student in the Doctor of Nursing Practice at North Dakota State University (NDSU). I am working together with my advisor, Heidi Saarinen, on a project to help increase colorectal cancer awareness and screening throughout the community of Jamestown. The purposes of this project are as follows:

- Increase the number of individuals receiving information on colorectal cancer and screening options for those ages 50-75 years of age by distributing informational brochures when present for flu vaccination at the Public Health Clinic or the Primary Health Clinic.
- Collect information about current knowledge and reasons for getting screened or not getting screened for colorectal cancer in the Jamestown area to aide future planning for improved screening processes through the Public Health Department.
- Help to improve screening rates for colorectal cancer in North Dakota to unscreened individuals ages 50-75 years of age.

The survey consists of fifteen questions with an anticipated time to complete of less than five minutes. There should be no risks involved in completing the survey. The results from the survey did help identify what is needed to improve CRCS rates in our community. Your participation is completely voluntary, and you can choose to quit taking the survey at any time. All surveys were anonymous and kept solely for the project. By completing the survey, you give consent to participate in the research for this project.

- If you have any questions regarding this project, please feel free to contact:
- Laura Bond- 701-231-7821 and leave a message
- Heidi Saarinen- heidi.saarinen@ndsu.edu
- If you have any questions about the rights of human participants in research or to report a problem, contact the NDSU IRB office at: 701-231-8995, or toll free: 855.800.6716, or e-mail ndsu.irb@ndsu.edu

Thank you for your time and participation, Laura Bond, DNP-S

#### **APPENDIX N. FIT COVER LETTER**

In order to be eligible for the CRCS kit, you must be between the age of 50 and 75 years of age, have never had screening within the last year, or had a colonoscopy within the last 10 years. If you are able to perform a CRCS kit and prefer the Primary Care Clinic involved in this project, the test that was provided is a simple, at home stool test called the fecal immunochemical test (FIT). The FIT can detect changes in your colon and rectum (intestines) by checking if there is any blood or cancer in your stool that would not otherwise be noticed by the naked eye. Blood in your stool could potentially mean you need further testing, such as a colonoscopy to help detect what changes are occurring in the colon and rectum. The FIT kit comes in a prepaid envelope with detailed instructions on how to obtain a stool sample. It is best to get a sample from the outer edges of your stool instead of the middle, as any changes that could be detected usually occur on the lining of the colon and rectum.

The results were communicated to you by the Primary Care Clinic. The researcher of this project did not have access to any of your personal information or access to your medical record or the actual results of this test. The author did only receive the return rate from the Primary Care Clinic and not your test results. The potential harm for this project is anxiety in awaiting colorectal cancer test results and did not require any invasive procedures. By completing the FIT, you give consent to participate in the research for this project.

If you have any questions or concerns regarding the results of your CRCS test, please feel free to contact: Lisa Clemens-1-844-663-1068. Thank you for your time and participation to help increase the CRCS rates in our community! Together we can help prevent, detect and treat colorectal cancer early.

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## APPENDIX O. FORMAL DOCUMENTATION FROM CLINICAL SITES

Robin Iszler <I Mon 10/30, 7:49 AM Bond, Laura; 'Robin I

Hello Laura – thank for the work you are doing with CVHD on the flu fit project. CVHD does not have a formal IRB committee and relies on the students to work with their education institutions for guidance on projects and studies to meet IRB approval. CVHD supports providing a learning environment where students are able look at population trends in order to improve health of the community. Your project fits with the mission of CVHD to make our community the healthiest place to live learn work and plan. This project is a partnership with Essentia clinic and clients who take test kits will be encouraged to follow up with their medical providers. Clients participation is completely voluntary.

I look forward to your partnership.



Robin Iszler, RN | Unit Administrator

Clemens, Lisa A. -Thu 11/2, 4:48 PM Bond, Laura ¥

Laura, per our conversation with Jennifer Erickson at Essentia Compliance, she did not require an IRB for your project. If you have any further questions please feel free to reach out and ask. Thank You!

Lisa Clemens RN, BSN, CDE

Certified Diabetic Educator/Nursing Supervisor

#### **APPENDIX P. IRB APPROVAL**

#### NDSU NORTH DAKOTA STATE UNIVERSITY

October 12, 2017

Dr. Heidi Saarinen School of Nursing

IRB Approval of Protocol #PH18082, "Colorectal Cancer Screening: A Collaboration with Public Health and Primary Care to Increase Colorectal Cancer Screening in a Rural North Dakota Community" Co-investigator(s) and research team: Laura Bond

Approval period: 10/12/2017 to 10/11/2018 Continuing Review Report Due: 9/1/2018

Research site(s): Essentia Health Clinic and other area sites in and around Jamestown, ND Funding Agency: n/a

Review Type: Expedited category # 7 IRB approval is based on the revised protocol submission (received 10/12/2017).

Additional approval from the IRB is required:

o Prior to implementation of any changes to the protocol (Protocol Amendment Request Form).
o For continuation of the project beyond the approval period (Continuing Review/Completion Report Form). A reminder is typically sent approximately 4 weeks prior to the expiration date; timely submission of the report the responsibility of the PI. To avoid a lapse in approval, suspension of recruitment, and/or data collection, a report must be received, and the protocol reviewed and approved prior to the expiration date.

Other institutional approvals:

· Research projects may be subject to further review and approval processes.

A report is required for:

o Any research-related injuries, adverse events, or other unanticipated problems involving risks to participants or others within 72 hours of known occurrence (Report of Unanticipated Problem or Serious Adverse Event Form). o Any significant new findings that may affect risks to participants. o Closure of the project (Continuing Review/Completion Report Form).

Research records are subject to random or directed audits at any time to verify compliance with human subjects protection regulations and NDSU policies.

Thank you for cooperating with NDSU IRB procedures, and best wishes for a successful study.

Sincerely, Krohy Shuley

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult www.ndsu.edu/irb. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD NDSU Dept 4000 | PO Box 6050 | Fargo ND SB108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

NDBJ is an EQUAL university.

#### **APPENDIX Q. IRB CONTINUING REVIEW REPORT**



Uate Received. 831201

INSTITUTIONAL REVIEW BOARD office: Research 1, 1735 NDSU Research Park Drive, Fargo, ND 58102 mail: NDSU Dept. #4000, PO Box 6050, Pargo, ND 58108-6050 p: 701.231.8995 f: 701.231.8098 e: ndsu.irb@ndsu.edu w: www.ndsu.edu/irb

#### Continuing Review Report

Use this form to: request a continuation of IRB approval if a protocol which is currently active (enralling or recruiting participants, providing study interventions, or collecting data from research participants which is not a part of nontine clinical care. If study remains open for data analysis of identifiable private information or identifishle

	Protocol Information	į
Protocol #: PH18082	Original approval date*: 10/12/2017	
Titles Colorectal Cancer Screening: A C	Collaboration with Public Health and Primary Care to Increase Colorectal Cancer Screening	

in a Rural North Dakota Community

Principal investigator: Dr.Heidi Saarinen	Co-investigator: Laura Bond
Department: School of Nursing	Department: Graduate Nursing
E-Mail/Campus Address: heidi.saarinen@sdsu.edu	E-Mail/Campus Address: lura.mepherson@ndsu.edu
Human Subjects Training: 10/20/17 (IRB office only)	Human Subjects Training: 4/3/17 (IBB office only)

I. Project Status

1. Expected end date of research: 08/10/19

2. Current research procedures involve: Recruiting participants

- Providing research intervention(s)
- Origoing data collection
- 🛛 Ongoing analysis of identifiable data

Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

3. Is the project currently externally funded?	🖂 No 📃 Yes	
If yes, source of current funding:	FAR#	
Current Funding period: Start date:	End Date:	

3a. Has a progress report been filed with the funding agency since last review?

Continuing Review Report NOSU Institutional Review Board Investoy 2018:

Page 1 of 4

Yes\* - Indicate approximately how many: Undetermined depending on how many show up at any given flu clinic.

Attach a copy of current consent form(s), and any recruitment materials.

4. Informed Consent: A copy of the approved informed consent form has been signed by each of the participants in the study, and retained for your records. Has this requirement been met?

Yes	
N/A, waiver approved	
No - explain	_

Have any potential participants declined to participate, or withdrawn from the research?
 No

Y	es.	- 6	xpl	air	K.

 Summarize any complaints about the research (and their resolution) since the last review? No complaints

#### B. Risk/Benefit Ratio:

- Summarize any unanticipated problems (even if previously reported) or adverse events that have
  occurred since the last review:
  - Note have occurred

<u>Unanticipated problem</u>: an unanticipated problem that involves risks to subjects or others is any incident, experience, or outcome that meets all the following criteria:

- is unexpected (in terms of nature, severity, or frequency) given the characteristics of the subject population and the research as described in the IRB approved protocol and consent document(s)
- is related, or possibly related to participation in the research
- suggests the research places subjects or others at greater risk of harm (physical, psychological, economic, or sociel harm) that previously known or recognized
- uney not base resulted in actual harm to subjects, but may only represent increased risk of harm (ic, physical, psychological, social, economic, legal).

<u>Adverse event</u>: any untoward or unfroorable medical occurrence (physical or psychological) in a human subject, including any abnormal sign, symptom, or discuse, temporally associated with the subject's participation in the research, whether or not considered related to their research participation. Such events may have dready been expected to occur with a certain frequency and severity, and previously identified as potential risks in the protocol form, and consent document(s).

Has any new information or additional risk(s) been discovered that would affect the risk/benefit ratio for new subjects (or for those currently or previously enrolled)?

No

Yes -explain, and indicate how this has been/will be addressed with future, current, or previously enrolled participants:

Contraining Reserve Report HOSU Institutional Reserve Goard Innouna 2018 Page 3 of 4

Investigator's Assurance
<ul> <li>As the Principal Investigator, I certify that:</li> <li>information provided in this report is complete and accurate</li> <li>each individual involved as a member of the research team possesses the necessary experience for conducting research activities in their assigned role, and is aware of and will abide by NDSU policies and procedures for the protection of research participants</li> <li>the research will be conducted according to the approved protocol</li> <li>IRB approval will be obtained prior to implementing changes in the research protocol, unless necessary to prevent immediate serious harm to participants</li> <li>all unanticipated problems involving risks to participants or others will be promptly reported to the IRB.</li> </ul>
- Submission of this report via the Principal Investigator's NDSU email constitutes an acceptable electronic signature.
Project is:
Approved, Project remains open for:     Data analysis, including analysis of identifiable private information or specimens, or     Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care
Complete/Inactive Retain records until
IRB Signature Kristy Shirley Date 9/21/2018
Reviewed by the Pull Board - meeting date
Expedited Review - Category: 7
Current approval period expires: 9[25]262.1
Next Report due": Stilleogd

& Data collection will be completed in Nov. 2018.

Continuing Americ Report NDSU institutional Basian Doard January 2018 Page 4 of 4

### **Oral Informed Consent Script**

Hello, we are participating in a project that is led by an NDSU graduate nursing student who is researching how to increase the number of adults being screened for colorectal cancer in our community. The recommended age to start colorectal cancer screening is at age 50 and through the age of 75, as this is the most at risk time to develop colorectal cancer. Colorectal cancer is the second leading cause of cancer related deaths in the United States that can be prevented, detected, and treated when caught early. Since you fall within the age group, would you like to receive more information about colorectal cancer and screening tools during your visit?

If you would like more information, we have an educational brochure and short survey to complete which will let us know if you are able to receive a colorectal cancer screening kit if you are willing to do this or your reasons for choosing not to be screened. The results for the survey will help identify what is needed to improve colorectal cancer screening rates in our community. All surveys will be anonymous and by completing the survey you give consent to participate in the research for this project. Your time and interest in this project are appreciated!

#### Information for FIT Testing

In order to be eligible for the colorectal cancer screening kit, you must be between the age of 50 and 75 years of age, have never had screening within the last year, or had a colonoscopy within the last 10 years. If you are able to perform a colorectal cancer screening kit and prefer the primary care clinic involved in this project, the test that will be provided is a simple, at home stool test called the fecal immunochemical test (FIT). The FIT can detect changes in your colon and rectum (intestines) by checking if there is any blood or cancer in your stool that would not otherwise be noticed by the naked eye. Blood in your stool could potentially mean you need further testing, such as a colonoscopy to help detect what changes are occurring in the colon and rectum. The FIT kit comes in a prepaid envelope with detailed instructions on how to obtain a stool sample. It is best to get a sample from the outer edges of your stool instead of the middle, as any changes that could be detected usually occur on the lining of the colon and rectum.

The results will be communicated to you by the primary care clinic. The researcher of this project will not have access to any of your personal information or access to your medical record or the actual results of this test. The author will only receive the return rate from the primary care clinic and not your test results. The potential harm for this project is anxiety in awaiting colorectal cancer test results and will not require any invasive procedures. By completing the FIT you give consent to participate in the research for this project.

If you have any questions or concerns regarding the results of your colorectal cancer screening test please feel free to contact: Lisa Clemens-1-844-663-1068. Thank you for your time and participation to help increase the colorectal cancer screening rates in our community! Together we can help prevent, detect and treat colorectal cancer early.

## Hello!

My name is Laura Bond and I am a graduate student in the Doctor of Nursing Practice at North Dakota State University (NDSU). I am working together with my advisor, Heidi Saarinen, on a project to help increase colorectal cancer awareness and screening throughout the community of Jamestown. The purposes of this project are as follows:

- Increase the number of individuals receiving information on colorectal cancer and screening options for those ages 50-75 years of age by distributing informational brochures when present for flu immunization at the public health clinic or the primary health clinic.
- Collect information about current knowledge and reasons for getting screened or not getting screened for colorectal cancer in the Jamestown area to aide future planning for improved screening processes through the Public Health Department.
- Help to improve screening rates for colorectal cancer in North Dakota to unscreened individuals ages 50-75 years of age.

The survey consists of fifteen questions with an anticipated time to complete of less than five minutes. There should be no risks involved in completing the survey. The results from the survey will help identify what is needed to improve colorectal cancer screening rates in our community. Your participation is completely voluntary and you can choose to quit taking the survey at any time. <u>All surveys will be anonymous and kept solely for the purpose of the project. By</u> <u>completing the survey you give consent to participate in the research for this project.</u>

- · If you have any questions regarding this project please feel free to contact:
  - o Laura Bond- 701-231-7821 and leave a message
  - o Heidi Saarinen-heidi.saarinen@ndsu.edu
- If you have any questions about the rights of human participants in research or to report a
  problem, contact the NDSU IRB office at: 701-231-8995, or toll free: 855.800.6716, or email ndsu.irb@ndsu.edu

Thank you for your time and participation, Laura Bond, DNP-S

#### **APPENDIX R. IRB: PROTOCOL AMENDMENT REQUEST**



Date Received

IRB Pr	stocol	£:
PH	808	3-

INSTITUTIONAL REVIEW BOARD office: Research 1, 1735 NDSU Research Park Drive, Farge, ND 58102 mail: NDSU Dept. #4000, PO Box 6050, Farge, ND 58108-6050 p: 701.231.8995 f: 701.231.8096 es ndsa.irb@ndsu.edu w: www.ndsu.edu/irb

#### Protocol Amendment Request Form

Changes to approved research may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate basards to participants. Reference: <u>SOP 7.5 Protocol Amendments</u>.

Examples of changes requiring IRB review include, but are not limited to changes in: investigators or research team vanishers, purpose/scope of research, recruitment procedures, compensation strategy, participant population, research setting, interpentions involving participants, data collection procedures, or surveys, measures or other data forms.

|--|

Protocol #: PH18082 Title: Colorectal Cancer Screening: A Collaboration with Public Health and Primary Care to Increase Colorectal Cancer Screening in a Rural North Dakota Community

Review category: Rempt

Expedited

Full board

Principal investigator: Dr.Heidi Saarinert Email address: heidi.saarinen@ndsu.edu Dept: School of Nursing

Co-investigator: Laura Bond Email address: laura.mcpherson@ndsu.edu Dept: Graduate Nursing

Principal investigator signature, Dates Herdi Saannen (Na email) 912/18

Description of propos	ed changes:
-----------------------	-------------

Date of proposed implementation of change(s)\*: 10/01/18
 <sup>1</sup>/
 <sup>1</sup>/

2. Describe proposed change(s), including justification:

The Public Health Site Administrator voiced concerns that the clinic is experiencing a large volume of adults presenting to the clinic for their flu immunization which is becoming difficult for the front desk staff to direct patients of the project to nursing or answer questions. To alleviate stress from the front desk staff, we would like to have a poster present in the Public Health Clinic displaying how to participate in the project, such as more information regarding the project, colorectal cancer, and how

Probacol Amendment Request Form NDSU Institutional Review Board Forre revised May 2015

Page 1 of 3 Last printed 09/27/2018 9:13:00 AM

to be screened. The Site Administrator believes this	would alleiviate a lot of	the stress by having a
poster along with having surveys available for patie	nts if they choose to fill t	hem out and will be
located by the poster.		

3. Will the change(s) increase any risks, or present new risks (physical, economic, psychological, or sociological) to participants?

and the	
DVCI	Niles
MOM &	DVO -
- A.	

Yes: In the appropriate section of the protocol form, describe new or altered risks and how they will be minimized.

4. Does the proposed change involve the addition of a vulnerable group of participants? Children: ⊠ no ☐ yes - include the Children in Research attachment form Prisoners: ⊠ no ☐ yes - include the Prisoners in Research attachment form Cognitively impaired individuals: ⊠ no ☐ yes\* Economically or educationally disadvantaged individuals: ⊠ no ☐ yes\*

\*Provide additional information where applicable in the revised protocol form.

5. Does the proposed change involve a request to waive some or all the elements of informed consent or documentation of consent?

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6. Does the proposed change involve a new research site?

🖂 no yes,

🛛 no

If information in your previously approved protocol has changed, or additional information is being added, incorporate the changes into relevant section(s) of the protocol. Draw attention to changes by using all caps, asterisks, etc. to the revised section(s) and attach a copy of the revised protocol with your submission. (If the changes are limited to addition/change in research team members, research sites, etc. a revised protocol form is not needed.)

Impact for Participants (future, current, or prior):

- Will the change(s) alter information on previously approved versions of the recruitment materials, informed consent, or other documents, or require new documents?
   No
  - Yes Attach revised/new document(s)
- Could the change(s) affect the willingness of currently enrolled participants to continue in the research?
   No

Protocol Americknept Request Porm NDSU Institutional Review Board Form revised May 2015 Page 2 of 3 Last printed 09/27/2018 9:12:00 AM, Yes - describe procedures that will be used to inform current participants, and re-consent, if necessary;

3. Will the change(s) have any impact to previously enrolled participants?

No Yes - describe impact, and any procedures that will be taken to protect the rights and welfare of participants:

FOR IRB OFFICE USE ONLY			
Request is: 🛐 Approved 🗌 Not Approved			
Review: Exempt, category#: Dispedited method, category # 7 Convened meeting, date: Expedited review of minor change			
IRB Signature: Knsty Shuley	Dute: 10/1/2018		
Comments: 0			
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Protocol Amendment Request Form NDSU Institutional Review Board Form revised Way 2015

