COLORECTAL CANCER: IMPROVING SCREENING COMPLIANCE WITH THE UTILIZATION OF FIT-DNA

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DOCTOR OF NURSING PRACTICE

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ABSTRACT

Colorectal cancer (CRC) is the second leading cause of cancer deaths in the United States (U.S.), but with the appropriate screening processes, this staggering fact can change (CDC, 2018). Routine CRC screening is one of the most powerful defenses in the fight against CRC, yet screening remains substantially underutilized (American Cancer Society, 2017). The United States Preventative Services Task Force (USPSTF) recommends screening those at average risk starting at age 50 and continuing to age 75 (USPSTF, 2016). Despite current recommendations, it is estimated that only 58.9% of qualifying women and 56.7% of qualifying men in the U.S. have been screened for CRC (Cooper & Gelb, 2016).

One proposed mechanism to improve CRC screening compliance is to offer patients screening options, keeping in mind that the best screening is the one that gets done (USPSTF, 2016). Fecal-immunochemical test-deoxyribonucleic acid (FIT-DNA) is a recently approved stool-based test that offers an additional screening choice for patients. The addition of FIT-DNA has the potential to increase CRC screening rates and providing education regarding current USPSTF recommendations could improve screening uptake.

The purpose of this quality improvement project was to implement and evaluate educational deliverables distributed to healthcare workers and patients within a local health system, and to analyze the influence of these deliverables on CRC screening rates and FIT-DNA utilization. Electronic memos were delivered to providers and staff regarding up-to-date screening recommendations. In effort to promote autonomy and informed decision-making, an electronic, printable educational tool was developed and distributed to patients at average risk for CRC. Data were collected on CRC screening rates and FIT-DNA utilization pre- and post-education implementation to evaluate if a positive trend existed.

Although there were statistical and evaluative limitations of the project, findings showed that the distribution of educational tools trended with an increase in CRC screening rates and FIT-DNA utilization. Based on results of the evaluation, education to providers, staff, and patients on current screening recommendations, and offering patients more screening options, can improve CRC screening compliance.

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CHAPTER 1. INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer fatalities in the United States (Centers for Disease Control and Prevention [CDC], 2016). It is estimated that one in three people with CRC will die from the disease (Doubeni, 2016). Although CRC is a serious threat to health, there are effective strategies to combat and prevent this cancer, one of which is CRC screening. According to the American Cancer Society (2016), CRC screening is considered "one of the most powerful weapons for preventing colorectal cancer," yet, screening is underutilized for a variety of reasons (Colorectal Cancer Screening Prevention section, para. 1). Despite evidence that verifies the effectiveness of CRC screening, the national screening rates remain low.

In effort to increase CRC screening rates, the American Cancer Society and the CDC established the National Colorectal Cancer Roundtable (NCCRT) in 1997 (American Cancer Society, 2017). The primary goal of the NCCRT is to increase usage of CRC screening mechanisms among appropriate populations. The NCCRT launched an action plan in March 2014 to reach an 80% screening rate of adults 50 years of age and older by the year 2018. Many hospitals, governmental agencies, and health plans have joined the NCCRT's efforts, including statewide formations of cancer coalitions.

As of 2014, national CRC screening rates of adults 50 years and older, ranged from 58% in the state of Wyoming to 76% in the state of Massachusetts (American Cancer Society, 2017). Out of the 50 states and the District of Columbia, North Dakota (N.D.) ranked 38th with a 63.6% screening rate for those at average risk (American Cancer Society, 2017). Currently in N.D., 42% of adults are not up-to-date with CRC screening (N.D. Department of Health, 2017). In effort to increase CRC screening rates in N.D., the American Cancer Society and the N.D. Department of Health developed the N.D. Colorectal Cancer Roundtable (NDCCRT). The NDCCRT encourages statewide organizations to join in the national initiative to screen 80% by 2018, and healthcare

facilities in N.D., including Sanford Health, are committing to the pledge (N.D. Department of Health, 2017). See Table 1 for a full list of N.D. organizations committed to the "80% by 2018" pledge.

Table 1

N.D. Organizations that Signed the "80% by 2018" Pledge

- Altru Health system
- Blue Cross Blue Shield of North Dakota
- Central Valley Health District
- Coal Country Community Health Centers
- Community Health Association of the Dakotas
- Custer Health
- Essentia Health
- Family HealthCare
- Great Plains Tribal Chairman's Health Board
- North Dakota Cancer Coalition
- North Dakota Department of Health
- North Dakota Medical Association
- Northland Community Health Center
- Quality Health Associates of North Dakota
- Sanford Health
- Sakakawea Medical Center
- Sargent County Health District
- Southwestern District Health Unit
- Trinity Health
- Valley Community Health Center

Note. Data obtained from N.D. Department of Health (2018).

The lack of CRC screening is a national health concern and states are acknowledging the need for action. Data shows that one-third of eligible adults in the U.S. have not been screened for CRC, and increased morbidity and mortality are resulting from a preventable disease (American Cancer Society, 2017). North Dakota is heeding the call to action, and efforts to increase CRC compliance are underway.

Significance of Project

Despite evidence supporting CRC screening, a high number of eligible individuals are not undergoing the recommended screening process. The latest report from the CDC (2017) states that from the years 2000-2015, CRC screening rates increased over time, however, they continue to remain below the target level of 80%. In 2015, the national screening rate was 62.4%, with the lowest screening utilization reported by those without health insurance (CDC, 2017).

The Affordable Care Act (ACA) requires private insurance plans to cover preventative services without any patient cost-sharing (CDC, 2017). One of the expert bodies that provides preventative recommendations is the United Sates Preventative Services Task Force (USPSTF) (CDC, 2017). The USPSTF is an independent panel composed of "16 experts in primary care and prevention who systematically review the evidence of effectiveness and develop recommendations for clinical preventative services," including CRC screening (Melnyk & Fineout-Overholt, 2015, p. 9). The USPSTF is sponsored by the Agency for Healthcare Research and Quality, and "its recommendations are considered the gold standard for clinical preventive services" (Melnyk & Fineout-Overholt, 2015, p.9). The USPSTF reports to the U.S. Congress on identified gaps between critical research and preventative services and suggests priority areas that merit further examination (USPSTF, 2016).

In June 2016, the USPSTF included a stool test called fecal-immunochemical test-deoxyribonucleic acid (FIT-DNA), in the CRC screening guidelines (Bibbins-Domingo, 2016). Because FIT-DNA, also known by its brand name Cologuard, was added to the USPSTF guideline recommendations, the ACA requires insurance companies to cover this screening mechanism, which will offer patients another CRC prevention strategy (American Cancer Society, 2017). The addition of another screening option will increase state and national CRC screening rates because "a

growing body of evidence demonstrates that offering patients different options substantially increases adherence to screening recommendations" (American Cancer Society, 2017, p. 17).

The national non-compliance rate prompted the USPSTF to update its recommendations in 2016 to emphasize the substantial evidence supporting CRC screening and its life-saving qualities, rather than emphasizing specific screening tests (American Cancer Society, 2017). This recommendation supports the message that any screening is better than no screening. One way to increase screening rates is to offer patients choices, as this promotes patient autonomy and screening compliance (Bibbins-Domingo, 2016). The USPSTF has expanded patient options by adding FIT-DNA as a valid screening choice. The USPSTF acknowledges that "offering a choice in colorectal cancer screening strategies may increase screening uptake," therefore, adding FIT-DNA to the screening option list has the potential to improve CRC screening compliance (Bibbins-Domingo, 2016, p. 2566).

Problem Statement

Nearly one-third of qualifying adults in the US have not been screened for CRC, and this increases the risk for preventable mortality rates among Americans (USPSTF, 2016). Screening prevents CRC through detection and removal of precancerous growths and it can detect cancer in its early stages, when treatment is often more successful (American Cancer Society, 2017). Through prevention and early detection, CRC screening reduces mortality and decreases health disparities (American Cancer Society, 2017). Despite the efficacy supporting CRC screening, many adults are not screened. The American Cancer Society (2017) predicts the number of new CRC cases to reach over a 140,000 in 2018, and an estimated 50,630 of these cases will result in death.

Sanford's CRC screening rates are in need of improvement, as screening rates remain below 80% (Sanford Health, 2016). Education on CRC screening, along with offering patients options, may effectively contribute to compliance uptake (American Cancer Society, 2017). The newest

edition to the recommended screening options is the stool-based test, FIT-DNA. The novelty status of FIT-DNA requires the delivery of education to healthcare providers, ancillary staff, and patients in order to increase awareness of current screening choices. Sanford Health has identified the need for educational materials to be delivered to its employees and patients regarding up-to-date CRC screening modalities, as the organization's CRC screening rates are below the 80% goal (Sandford Health, 2016). Addressing the educational needs of staff and patients, and offering patients choices, has the potential to improve screening rates, in return, decreasing CRC deaths (USPSTF, 2016).

Project Description

This quality improvement project evaluated the effectiveness of education delivered to Sanford providers, staff, and patients on recommended CRC screening mechanisms, with an emphasis on the recently approved FIT-DNA screening option. In effort to increase CRC screening compliance, Sanford Health, among the other N.D. organizations listed in Table 1, have joined the "80% by 2018" pledge (N.D. Department of Health, 2018). Sanford Health is the largest rural, non-profit health system in the U.S. (Sanford Health, 2016). The Sanford Enterprise has multiple locations located in more than 126 communities that are divided into four regions (Sanford Health, 2016). The four regions consist of the following listed in alphabetical order: (a) Bemidji, Minnesota, (b) Bismarck, N.D., (c) Fargo, N.D., and (d) Sioux Falls, South Dakota (Sanford Health, 2016).

FIT-DNA was made available for Sanford providers to electronically order within the Epic system in June 2017, as this was when FIT-DNA would be covered by a majority of insurers. Prior to its debut, education to Sanford staff was provided throughout the enterprise via written deliverables in the form of memos. The first memo was released in February 2017 via Sanford portal and email system with the target audience identified as primary care providers and therefore entitled the "provider memo" (Appendix A). The second memo, or "nurse memo," was released in March 2017 via email with the target audience of nursing staff, medical assistants, and other

healthcare workers who assist providers in CRC screening and ordering (Appendix B). Both memos included up-to-date CRC screening recommendations and statistics regarding Sanford's screening compliance, and the memos were tailored to address role-specific actions to help improve screening rates.

In addition to educating Sanford staff on CRC screening modalities, Sanford patients also received up-to-date information on CRC screening options. A patient education tool was created and approved in September of 2017 (Appendix C). The tool consisted of current screening recommendations for those at average risk for CRC, along with a brief explanation of the processes involved with each test. The fecal immunochemical test (FIT), FIT-DNA, and colonoscopy were included on the tool, as FIT and colonoscopy are commonly chosen forms of screening and FIT-DNA is new, necessitating current information (American Cancer Society, 2017). The patient education tool was distributed in October 2017 to all Sanford regions via newsletters, emails, Epic software, and share point. The tool could then be printed and hand-delivered to patients or reviewed electronically.

Project Purpose

This project's purpose is to attain health promotion and disease prevention via the distribution of screening education and advocation for patient autonomy. Knowledge of current CRC screening recommendations, identification of barriers to the screening process, and offering patients choices can increase screening compliance (USPSTF, 2016). The goal of this quality improvement project is to educate providers, staff, and patients on evidence-based CRC screening options via educational tools. Improving CRC screening knowledge among Sanford's employees and patients can lead to increased screening compliance, while consequently decreasing negative health outcomes related to CRC.

Project Objectives

The goal of this quality improvement project was to determine whether implementing education to providers, staff, and patients, regarding CRC screening options, specifically the new option of FIT-DNA, is an effective strategy in increasing screening compliance for adults ages 50-75 at average risk for CRC within the Sanford Enterprise. The objectives include:

1. Develop and implement educational materials regarding recommended CRC screening options to Sanford employees and patients.
2. Increase Sanford's regional and enterprise CRC screening rates to a minimum of 80% by January 2018.
3. Increase Sanford's utilization of FIT-DNA by January 2018.

CHAPTER 2. LITERATURE REVIEW AND THEORETICAL FRAMEWORK

A literature review was conducted in order to synthesize current information relating to CRC screening modalities, barriers to screening, and educational mechanisms to increase screening compliance. Qualitative and quantitative studies, along with clinical practice guidelines, were examined in effort to achieve a thorough analysis of the subject. The purpose of the literature review was to examine what is known about current CRC screening recommendations, potential barriers to the screening processes, the need for and effectiveness of provider, staff, and patient education, as well as any implications to the nurse practitioner.

The literature review process was completed by analyzing a variety of sources through the process of a database search. The databases explored include: Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, and National Guideline Clearing House (NGC). The databases were examined utilizing the following criteria: publication date between the years of 2010-2017, peer-reviewed, written in the English language, full text availability, and information pertaining to adults at average risk for CRC. Exclusion criteria included information related to those younger than 50, and those at an increased risk for developing CRC. The following keywords were searched: *adult, colorectal cancer, screening, risk, primary care, colonoscopy, FIT, FIT-DNA, Cologuard, compliance, USPSTF,* and *guidelines*.

The database search for CRC screening in CINAHL and MEDLINE individually yielded over 950 results, for a combined total of 2,968 articles. The NGC database search resulted in 47 articles. Search results were narrowed to include details focusing on adults at average risk for CRC, barriers to the screening process, FIT-DNA stool test, and educational mechanisms to increase knowledge of patients, providers, and staff. The following literature review organizes information into categories pertinent to the previously stated project objectives and implications for the nurse practitioner.

Pathophysiology and Epidemiology

In order to fully recognize the significance of CRC screening, it is helpful to review the physiological process of the disease. Colorectal cancer most often develops from adenomatous polyps that are described as major precursors in the development of CRC (Allameh, Davari, & Emami, 2011). Polyps are defined as any protrusion into the lumen of the gastrointestinal tract that can be harmless at first, but over time may develop into cancer (Mayo Clinic, 2018). Many polyps are asymptomatic, and patients may or may not display clinical manifestations of CRC (Mayo Clinic, 2018). Although these polyps are often precursors to malignancy, they can be removed (Allameh, Davari, & Emami, 2011). Colorectal cancer can be difficult to diagnose because symptoms of a troublesome polyp may not present until the cancer has become advanced (Allameh, Davari, & Enami, 2011). Early detection is directly related to better outcomes, and polyp removal can prevent and/or detect CRC early enough to be curable (Allameh, Davari, & Emami, 2011). Colorectal cancer is a common, deadly cancer, accounting for the second highest cancer fatalities in the nation (CDC, 2016). Routine screening processes are therefore invaluable and life-saving (American Cancer Society, 2016).

Screening Recommendations and Modalities

It is widely accepted that the initiation of routine CRC screening processes begins at age 50 (Atkinson, et al., 2015). The USPSTF, a panel of experts that makes evidence-based recommendations on preventative screening, assigns a letter grade to each recommendation statement using five letters: A, B, C, D, or I (USPSTF, 2016). The grade A letter indicates substantial evidence supporting the recommendation, grade B indicates moderate to substantial evidence supporting the recommendation, grade C indicates at least moderate supporting evidence, grade D indicates evidence against the service, and grade I concludes that evidence is insufficient to

support the service (USPSTF, 2016). These grades indicate the strength of evidence supporting a preventative service, such as CRC screening (USPSTF, 2016).

The USPSTF (2016) recommends, with grade A evidence, the screening of men and women at average risk for CRC to begin at age 50 and continue until age 75. CRC screening should continue until age 75, as benefits to screening those 76 and older are individually based and depend on the patient's overall health (USPSTF, 2016). Routine screening of adults 86 years of age and older is not recommended as the benefits do not outweigh the risks (USPSTF, 2016). Recommended screening modalities include stool-based tests and direct visualization tests (USPSTF, 2016). The USPSTF (2016) purposefully does not list the screening tests in any preferred order because the best screening method is the one the patient will complete. Therefore, the goal is to maximize screening by giving patients choices, and the USPSTF predicts that providing screening options to patients will have the greatest effect on reducing CRC deaths (USPSTF, 2016).

Strong evidence supports CRC screening and its potential to prevent malignancy and decrease mortality for both men and women (Atkinson et al., 2015). Multiple screening modalities are available including: guaiac fecal occult blood test (gFOBT), FIT, FIT-DNA, colonoscopy, computed tomography (CT) colonography, and sigmoidoscopy (Allameh, Davari, & Enami, 2011). Each screening test has different frequency guidelines, however, in the event a screening test is positive, a follow-up colonoscopy is almost always recommended (USPSTF, 2016).

Stool-based tests are defined as the gFOBT, FIT, and FIT-DNA. The gFOBT and FIT are recommended to be completed on an annual basis (USPSTF, 2016). The gFOBT uses a chemical to detect hemoglobin in the stool, however the test is unable to differentiate where the microscopic blood originated from in the colon. Therefore, if the gFOBT is positive, a colonoscopy is needed to make a diagnosis and determine the cause of bleeding (Rex, 2016). The FIT is considered to be more accurate than the gFOBT, because the FIT uses a different technology to detect microscopic

blood in the stool. The FIT method uses antibodies to detect gastrointestinal bleeding and is more specific to detecting hemoglobin in the lower digestive tract, causing it to be more accurate (van Lanschot et al., 2017). However, the sensitivity of FIT is not 100%, because not all CRCs bleed (van Lanschot et al., 2017). If FIT is positive, a follow-up colonoscopy is again recommended to make a diagnosis and determine the cause of bleeding (Rex, 2016). The FIT-DNA test is also stool-based, and because of its significance in this particular project, it will be discussed in detail later.

Direct visualization tests include colonoscopy, CT colonography, and flexible sigmoidoscopy. A colonoscopy is a procedure completed by a provider, where a flexible tube with a camera is used to visualize the colon. The process requires sedation and bowel preparation with risks including perforation, bleeding, and an adverse reaction to sedation medications (Mayo Clinic, 2018). The colonoscopy is a highly effective detection and screening tool, and if the test is negative, the average patient is due to be re-screened in ten years (USPSTF, 2016). The CT colonography is a mechanism that uses radiation to gain an internal view of the large intestine (Rex, 2016). This test requires bowel preparation but does not require sedation. The cost-effectiveness of this test is a concern, as extracolonic findings are often detected, and can lead to unnecessary workup. The CT colonography is considered diagnostic, but if polyps are detected, a colonoscopy will be needed to remove the polyps (Rex, 2016). If the CT colonography is negative, repeat testing in five years is recommended (USPSTF, 2016). The flexible sigmoidoscopy is also a direct visualization test that is often paired with the FIT test to increase successful detection (USPSTF, 2016). The flexible sigmoidoscopy visualizes the rectum and lower colon, therefore has significant limitations in relation to identifying polyps in the entire colon (Mayo Clinic, 2018). Bowel preparation is recommended and one of the risks of this test includes bleeding (Mayo Clinic, 2018). If the test is negative, repeat screening in five years is recommended (USPSTF, 2016). If positive, a follow-up colonoscopy to view the entire colon is advised (Mayo Clinic, 2018).

Cost

The cost of CRC screening is convoluted by continuing healthcare reform (Green, Coronado, Devoe, & Allison, 2014). In 2010, when the Affordable Care Act was passed, the majority of insurances were required to cover USPSTF-recommended screening costs without deductible or co-payment (Redberg, 2016; U.S. Department of Health and Human Services, 2018). Patients who have Medicare Part B currently have coverage on all USPSTF-recommended screening options (U.S. Centers for Medicare and Medicaid Services, n.d.). The best way to address CRC screening cost for those with private insurers is to encourage patients to verify CRC screening coverage with their insurance, keeping in mind that the uninsured are also eligible for CRC screening coverage in some states (U.S. Department of Health and Human Services, 2018).

With evolving healthcare reform, studies analyzing CRC screening costs are often outdated upon publishing, but it is useful to look at trends. Of the CRC screening methods available, colonoscopy is considered the most expensive (Redberg, 2016). The higher cost of the colonoscopy is due to a variety of reasons. The colonoscopy is often completed in a surgery center and billed as a procedure or operation (Redberg, 2016). The use of sedation and biopsies can also drive up costs of colonoscopies (Redberg, 2016). According to Pyenson, Scammell, and Broulette (2014), the "average allowed cost in 2010 for screening colonoscopy was $2,146 for commercial payers and $1,071 for the Medicare population, with average cost sharing of $334 and $275, respectively" (p.2). The average pre-coverage cost for the flexible sigmoidoscopy is $520, $439 for the CT colonography, $649 for FIT-DNA, and $22 for FIT (Exact Sciences Corporation, n.d.; Green et al., 2014; Pyenson, Scammell, & Broulette, 2016).

To date, health plans that started after September 2010, are required to cover CRC screening tests (American Cancer Society, 2018). This may or may not change in the face of healthcare reform, however, despite continuous healthcare evolvement, screening remains the best economical

choice. The cost of screening pales in comparison to the cost of CRC treatment, which was estimated at "$43,000 within the first 12 months after diagnosis, not including prescription drug expense" (Pyenson, Scammell, & Broulette, 2016, p. 11). Cost is an important consideration, but it should not prevent patients from the being screened while the Affordable Care Act remains in place.

Risk Factors

In addition to screening processes, various factors have been identified that assist in calculating a person's risk for developing CRC and choosing the appropriate screening process. Risk factors identified include, but are not limited to: advancing age, gender, race/ethnicity, lifestyle, environmental exposures, personal history of chronic bowel disease, and family history (Scully & Cheung, 2016). Of all the identified risk factors, age, is one of the greatest influences associated with the development of CRC (Scully & Cheung, 2016).

The risk for CRC advances with age and "more than 90% of cases are diagnosed in individuals 50 or older" (Scully & Cheung, 2016, p. 114). The annual incidence of CRC accelerates after age 40, and doubles each decade until age 80 (USPSTF, 2016). Young adults may also develop CRC, however, it is more common in ages 50 or older (American Cancer Society, 2017). The identified risk factor of advancing age has impacted the CRC screening recommendations, and the American Cancer Society (2017) recommends that men and women, who are at average risk, start screening at age 50.

Lifestyle risk factors include modifiable elements such as diet, obesity, physical inactivity, smoking, and excessive alcohol consumption (Scully & Cheung, 2016). Diets high in fat, processed meats, and red meats, and low in fiber have been associated with an increased CRC risk (Angelo et al., 2017). Obesity and physical inactivity have also been linked CRC, as the "highest incidence rates are seen in affluent nations where obesity and sedentary lifestyles are common" (Erdrich, Zhang, Giovannucci, & Willett, 2015, p. 1272). Additionally, a long-time smoking history and

heavy alcohol use are linked to CRC. Lifestyle factors should be taken into consideration when teaching patients about CRC, as changes can be made to lessen their risk for CRC (American Cancer Society, 2017).

In addition to age and lifestyle, genetics and a personal history of chronic bowel disease are also risk factors. A hereditary predisposition leads to an increased likelihood of developing CRC (Johnson et al., 2013). The probability increases to greater than 15% in a person who has a first-degree relative with CRC, compared to an average population risk of 5% (Johnson et al., 2013). Genetic syndromes, such as Lynch syndrome (hereditary-non-polyposis colorectal cancer), increases the risk for CRC development (American Cancer Society, 2018; CDC, 2016). Lynch syndrome is an inherited condition that increases one's risk for many types of cancer including pancreas, kidney, prostate, ovary, and breast (American Cancer Society, 2018). The overall risk for CRC development in those with Lynch syndrome can be as high as 80% depending on which gene is affected (American Cancer Society, 2018).

Those with a personal history of inflammatory bowel disease (IBD), such as ulcerative colitis or Crohn's disease, may also predispose individuals to CRC, however some studies have shown that modern treatments for IBD lessen the severity of the disease, which may also decrease CRC risk (Johnson et al., 2013). Other risk factors continue to be studied and identified, such as environmental and occupational exposures to carcinogens that can increase one's chances of developing CRC (Scully & Cheung, 2016).

Treatment and Prognosis of CRC

Treatment options for CRC vary according to the location and extent of tissue invasion (Damm, Vogel, & Prenzler, 2014). The choice of therapy affects prognosis and quality of life, therefore should be carefully considered (Damm, Vogel, & Prenzler, 2014). Treatment ranges from surgery, chemotherapy, radiation, and palliative care without life extension (Damm, Vogel, &

Prenzler, 2014). Survival and treatment benefits decline with increasing age and comorbidity (Van Eeghen, Bakker, van Bochove, & Loffeld, 2015). The most effective treatment is usually surgery to remove the malignant tumor and adjacent tissue and lymph nodes that may contain cancer cells (Lisovsky et al., 2017). Chemotherapy and radiation are used as supportive measures in addition to surgical intervention, however, advancements are constantly being developed to improve prognosis (Damm, Vogel, & Prenzler, 2014).

Prognosis of CRC varies, but early detection is associated with a better outcome. The five-year survival rate can help estimate a patient's prognosis but is not an exact measurement or predictor of a patient's personal lifespan (American Cancer Society, 2017). The five-year survival rate is a calculated percentage of patients who live at least five years after a cancer diagnosis (American Cancer Society, 2017). The five-year survival rate of CRC is directly related to the extent of tissue invasion (American Cancer Society, 2017). CRC cancer is staged using the tumor node metastasis (TNM) classification, and the five-year survival rate for stage I is about 92% while the five-year survival rate for stage IV is about 11% (American Cancer Society, 2017). These rates demonstrate that early detection leads to better outcomes, emphasizing the importance of CRC screening.

Barriers to CRC screening

Barriers to CRC screening vary from person to person and may include a variety of factors. A number of reported patient barriers to CRC screening have been identified and include the following:

- Lack of provider recommendation
- Lack of perceived need to complete screening
- Knowledge deficit
- Financial barriers

- Lack of health insurance
- Fear of cancer diagnosis
- Discomfort with bowel and dietary preparations
- Embarrassment
- Reluctance of handling his/her feces for fear it is unsanitary
- Fear of invasiveness
- Inconvenience of arranging transportation
- Fear of anesthetics and sedation medications
- Perceived fear from some males that screening implies a homosexual act and threatens masculinity
- Confusion and difficulty differentiating medical tests

(Joseph, King, Miller, & Richardson, 2012; Gwede et al., 2015).

The above barriers vary by test (Joseph et al., 2012). For example, a patient is more likely to refuse stool-based tests due to reluctance of handling stool, while refusal of direct visualization tests would more likely be due to fears related to bowel preparation and/or sedation (Gwede et al., 2015; Joseph et al., 2012). Because barriers vary by patient and by screening mechanism, it is important not to assume a patient's reasoning for screening reluctance and to review all viable options with the patient.

Patient barriers are not the only roadblocks, clinicians also experience obstacles that can hinder the screening process. Provider barriers to CRC screening include "lack of knowledge of current screening guidelines, forgetfulness, competing priorities in the care of the patient, patient refusal, lack of time, lack of a reminder system, and lack of tracking and follow up systems" (Joseph et al., 2012, p. 55). Muliira et al. (2016) suggest that the lack of knowledge regarding CRC

screening guidelines among providers and nurses is a major barrier to CRC screening rates and compliance. Continuing education of providers and nurses is recommended as, "further educational efforts targeting health care professionals is still valid in the fight against CRC because the lack of knowledge is still common and contributing to the underutilization of screening" (Muliira et al., 2016, p. 105). Barriers may be addressed and overcome with effective educational tools and system modifications. Healthcare organizations should work as a team in assisting providers to reach health maintenance goals.

FIT-DNA

The database search incorporating the search words FIT-DNA and Cologuard yielded significantly less results. CINAHL produced three articles and MEDLINE produced one article pertaining to FIT-DNA under the previously described search methods. The one article found in MEDLINE was also one of the three articles found in CINAHL.

The most recent article gives an introduction into a proposed observational cross-sectional cohort study that will be conducted in the Netherlands. Van Lanshot et al. (2017) hypothesizes that Cologuard or FIT-based surveillance is a "cost-effective first-line surveillance strategy" for CRC screening (p. 2). The authors plan to include 4,000 individuals between the ages of 50 and 75 and stool samples will be collected for FIT and FIT-DNA testing prior to a scheduled colonoscopy. The diagnostic results of the FIT and FIT-DNA testing will be compared to the colonoscopy and will also determine the cost-effectiveness of the least invasive screening mechanisms (van Lanshot et al., 2017).

Levine and Goldschlag (2014) discussed the importance of "cell-free nucleic acids as noninvasive biomarkers in oncology" (p. 44). The authors link the advancements made with FIT-DNA to future detection of other disease processes, including gynecological malignancies. The authors anticipate that the cell-free DNA testing will be important in the future of medicine (Levine

& Goldschlag, 2014). The technology is becoming more cost-effective, specific, and sensitive to disease processes and these benefits have the potential to revise future screening guideline recommendations (Levine & Goldschlag, 2014).

The third article was published, in 2014 in a nursing journal, no authors were listed, and two references were cited. The brief article discussed the importance of genomics in medicine. Genomics is type of molecular biology that studies genetic sequencing and has led to advancements in oncology (American Cancer Society, 2018). Although FIT-DNA is not a genetic test, the article states the advancement of FIT-DNA testing may improve future screenings processes ("Patient Recall," 2014). This is important because developments in the screening or treatment of one type of cancer may pertain to other cancers as well ("Patient Recall," 2014).

The NCG resulted in 13 guideline summaries when searching the term FIT-DNA. Of the 13 results, four guideline summaries pertained to CRC, one of which was a guideline synthesis. All results were published in 2016. The first guidelines addressed recommended surveillance after a CRC resection, which is was not congruent with this project's target population of those at average risk (Kahi et al., 2016). The second guideline summary was recommended by the Canadian Task Force on Preventative Health Care (CTFPHC), which does not recommend colonoscopy as a primary screening test for CRC (2016). The CFPHC also recommends screening adults ages 60 to 74 with gFOBT or FIT every two years or flexible sigmoidoscopy every ten years (CTFPHC, 2016). FIT-DNA was briefly mentioned in the guidelines as needing more information before recommending (CTFPHC, 2016).

The third guideline summary obtained from NCG was the USPSTF recommendations on CRC screening, which were updated in June 2016 (Bibbins-Domingo et al., 2016.) The USPSTF concludes with "high certainty that screening for colorectal cancer in average-risk, asymptomatic adults aged 50 to 75 years is of substantial net benefit" (Bibbins-Domingo et al., 2016, p. 2564).

The USPSTF includes FIT-DNA as a valid screening modality, acknowledging that is more sensitive, yet less specific, than FIT (Bibbins-Domingo et al., 2016).

What is FIT-DNA?

Cologuard is the brand name for FIT-DNA, and it is a single stool test that is specialized in detecting abnormal cells shed by the lining of the colon (Exact Sciences Corporation, n.d.). Through a molecular process, FIT-DNA can detect cancerous or precancerous DNA in the stool that is obtained via a sample kit that is sent directly to the patient's home. The kit is accompanied by a prepaid and addressed United Parcel Service return label for patient's mailing convenience. The FIT-DNA company then releases results to the patient's ordering provider (Exact Sciences Corporation, n.d.). If results are negative, the patient is due to be re-screened in three years, and if results are positive, a follow-up colonoscopy is recommended (Exact Sciences Corporation, n.d.; MN Community Measurement, 2016). The FIT-DNA test is evidence-based and approved by the Food and Drug Administration (FDA) (Bibbins-Domingo et al., 2016). As of June 2016, FIT-DNA has been included in the USPSTF colon cancer screening guidelines (Bibbins-Domingo et al., 2016).

Exact Sciences Corporation is a molecular diagnostics company based out of Wisconsin that manufactures Cologuard, which is the only FIT-DNA screening test available in the U.S. (Bibbins-Domingo et al., 2016). Exact Sciences funded a large clinical trial, consisting of 12,776 participants within 90 sites throughout the U.S. and Canada (Imperiale et al., 2014). The clinical trial was a cross-sectional study that took place from June 2011 to November 2012, and institutional review board (IRB) approval was obtained from each site (Imperiale et al., 2014). The target population consisted of asymptomatic individuals between the ages of 50 and 84, at average risk for CRC, scheduled for a screening colonoscopy (Imperiale et al., 2014). Prior to the colonoscopy, participants provided a stool specimen that underwent FIT and FIT-DNA testing. Of the 12,776

participants, 9,989 (78.2%) had results that could be effectively evaluated (Imperiale et al., 2014). Results indicated that FIT-DNA testing detected more cancers than FIT, however, FIT-DNA was less specific, resulting in more false positives than FIT (Imperiale et al., 2014). However, this clinical trial was largely successful and led to its approval by the FDA, American Cancer Society, and the USPSTF.

Educational Tools

When examining the implementation of educational tools for patients, it is helpful to recognize patient motivators for screening. A variety of patient motivators have been identified and include age, family, provider, media, benefits of early detection, and known risk factors (i.e. family history) (Gwede et al., 2015). In order to deliver effective patient education, these motivators should be addressed with educational tools.

In addition to addressing patient motivators, it is also important to keep patient information concise. Educational tools are beneficial if straight-forward, as complex and intricate information can be overwhelming (Smith et al., 2014). This can be particularly true when referring to complex statistics, as some patients are skeptical of statistics or not confident in determining how statistics relate to them (Smith et al., 2014). Some statistics may be effective and enlightening, however, interventions focused on improving the comprehension of the outcomes without "detailed statistic information" may have a positive impact on educational goals (Smith et al., 2014, p. 520).

Educational tools should also offer the patient options. Offering patients choices in screening mechanisms has shown to increase screening compliance (Bibbins-Domingo, 2016). Presenting options with patient education tools "have shown to be effective in helping people make informed choices about their health by incorporating balanced information on the benefits and harms of healthcare options, together with methods to clarify preferences" (Smith et al., 2104, p. 512). Offering choices promotes patient autonomy and implementing an education tool that the

patient can review independently or with a provider leads to informed decision-making and better outcomes (Smith et al., 2014).

Providers should also take care not to underestimate their influence on patients. Patients value the education that provider's deliver, as studies have shown that provider influence weighs heavily on patients' medical decisions (Gwede et al., 2015). Gwede et al. (2015) completed a qualitative study exploring perceptions of patients presented with CRC screening options and concluded, "Similar to past research, they [patients] acknowledged that health-care provider discussion and encouragement to screen for CRC was one of the more influential methods to encourage CRC screening" (p.298).

Patient education is greatly instrumental in decreasing screening barriers, however, provider and staff education are also a priority. Continuing education for providers and other healthcare workers is essential because of the unique dynamics of healthcare and its constant evolvement (Melnyk & Fineout-Overholt, 2015). When educating providers and staff on CRC screening options for patients, it is important to stress the significance of patient autonomy as, "Awareness of patients' test-specific preferences may also facilitate communications for encouraging test utilization to improve screening rates" (Gwede et al., 2015, p. 299). Education to providers and staff should emphasize the message that the best screening is the one that gets done, and that patient autonomy and offering patients options can lead to increased screening rates and save lives.

Health Promotion and Disease Prevention

Health promotion and disease prevention are mainstay goals of primary care, and CRC screening compliance contributes to these desired health outcomes (World Health Organization [WHO], 2018). Disease prevention is a "behavior motivated by a desire to actively avoid illness, detect it early, or maintain functioning within the constraints of illness" (Pender, Murdaugh, & Parsons, 2011, p. 5). An increasing emphasis on disease prevention has resulted in the development

of guidelines for preventative services, and education on current guidelines regarding CRC screening options can contribute to disease prevention (Ely et al., 2016; Pender, Murdaugh, & Parsons, 2011).

While promoting health and preventing disease are seemingly mutually inclusive, health promotion is described in as "the process of enabling people to increase control over, and to improve, their health" (WHO, 2018, Health Promotion section, para.1). This project focuses on health promotion by empowering patients to make informed decisions about CRC screening options. The WHO (2018) advocates for health literacy by stating, "People need to acquire the knowledge, skills, and information to make healthy choices…they need the opportunity to make those choices" (What is Health Promotion section, para. 4). Patients are provided education and guidance on the recommended screening options, but the patient will ultimately determine his or her own health behavior. Education to promote health literacy and offering the patient options contributes to health promotion by enabling patients to make informed, healthy choices (WHO, 2018). Health promotion and disease prevention share numerous goals, both aimed toward achieving optimal health. Increasing knowledge and awareness of CRC screening recommendations among providers, staff, and patients, can contribute to positive health outcomes.

Implications for the Nurse Practitioner

The American Association of Colleges of Nursing (AACN) (2017) describes the Doctor of Nursing Practice (DNP) profession as one rooted in evidence-based practice, quality improvement, and leadership. The nurse practitioner's (NP) role is to implement scientific-based care to promote quality outcomes (AACN, 2017). Offering preventative screening measures is evidenced-based and associated with disease prevention and health promotion. Because most cancer screening tests are initiated within primary care provider offices, it is crucial that the NP remain abreast of current

recommendations in order to achieve optimum outcomes (Haggstrom, Klabunde, Smith, & Yuan, 2013).

As previously stated, NP's play a vital role in patient education, and patients value medical advice delivered by providers (Gwede et al., 2015). Nurse practitioners have a professional duty to provide patients with comprehensive education in order to guide informed decision-making. Comprehensive education in regard to CRC screening should include the "benefits, harms, effectiveness, safety, and costs of options available to screen for colorectal cancer" (Randel, 2012, p. 2). Applying evidence-based practices, by promoting CRC screening mechanisms, fulfils the NP's role in providing quality, evidence-based care that improves health outcomes.

Theoretical Framework

A theoretical framework is "the basis upon which a study is guided" (Melnyk & Fineout-Overholt, 2015, p. 611). The diffusion of innovations theory, developed by Everett M. Rogers, attempts to disseminate the gap between evidence-based research and clinical practice (Pender, Murdaugh, & Parsons, 2011). The framework explains "the process of innovation and the various stages involved in adopting a new idea, thereby narrowing the gap between what is known and what is put to use" (Pender, Murdaugh, & Parsons, 2011, p. 76). The diffusion of innovations theory has been applied to various academic disciplines and assists in outlining the process through which new research and technologies become utilized in general practice (Murray, 2009).

The diffusion of innovations theory is utilized in this project to disseminate the gap between research-based CRC screening mechanisms and the lack of implementation in widespread practice. There is evidence to support the usage of FIT-DNA stool tests as an effective CRC screening modality, however, it has not been widely utilized in the clinical setting. The diffusion of innovations theory describes diffusion as "the process through which an innovation is communicated through certain channels, over time, among members of a social system" (Pender,

Murdaugh, & Parsons, 2011, p. 76). Through the channels of communication, new ideas, such as FIT-DNA technology, are disseminated to promote health and widespread change.

There are four main elements of diffusion: (a) innovation, (b) communication channels, (c) time, and (d) the social system (Pender, Murdaugh, & Parsons, 2011). Innovation is the new idea, or the idea that is perceived to be new. Communication is how the new idea spreads. A new idea is rarely adopted immediately, therefore, the passage of time is necessary for the innovation to be accepted and utilized (Pender, Murdaugh, & Parsons, 2011). The social system includes both internal and external factors that influence potential adopters. These four elements influence the dissemination and acceptance of a new idea, and this process relies greatly on human capital (Murray, 2009).

When applying the four main elements of diffusion to the CRC project, innovation is identified as the FIT-DNA stool test. The communication channels include media and interpersonal communication. Time varies with each educational tool, however, successful diffusion is predicted over a 12-month period, as evidenced by increased CRC screening numbers and FIT-DNA utilization. The social system includes, but is not limited to, guideline recommendations, cancer coalitions, hospital leaders, and patient-provider relationships.

When utilizing the diffusions of innovations theory, it is useful to recognize the five adopter categories that help describe the innovativeness of an individual, organization, or system (Pender, Murdaugh, & Parsons, 2011). The five adopter categories are: (a) innovators, (b) early adopters, (c) early majority, (d) late majority, and (e) laggards (Pender, Murdaugh, & Parsons, 2011). Innovators are information seekers and the first to adopt a new idea. Early adopters are judicious in choice of adoption and often hold a high social and leadership status. Early majority adopters deliberate and cautiously accept innovations. Late majority adopters are more skeptical and adopt a new idea after the general majority. Laggards need proof that an innovation will not fail and are generally opposed

to change. Laggards are the last to adopt a new idea (Pender, Murdaugh, & Parsons, 2011). The above descriptions of adopter categories aid in understanding the variability of innovation adoption and complexities associated with change.

The diffusion of innovations theory can help explain the process of FIT-DNA dissemination, and the rate of which the new idea is accepted. Despite evidence supporting FIT-DNA effectiveness, it is not widely utilized in the clinical setting. Innovation diffusion can be difficult, and as the model developer, Rogers, states, "Getting a new idea adopted, even when it has obvious advantages, is difficult" (Murray, 2009, p. 108). The gap between research and practice can be connected, however, it will likely never be fully cohesive as "the number of variables is far greater than could ever be realistically examined" (Murray, 2009, p. 115). Research and innovation, along with clinical judgement, can help guide clinical practices and health promotion.

In addition to the diffusion of innovations theory, the Plan-Do-Study-Act (PDSA) method also guided this quality improvement project. Plan-Do-Study-Act is a cyclic model that is used in "active-oriented learning" that has shown to be useful in many quality improvement projects (Melnyk & Fineout-Overholt, 2015, p. 83). The four cycles of plan, do, study, and act put a "planned change into effect" on a smaller scale and then learn from its impact (Melnyk & Fineout-Overholt, 2015, p. 83). The PDSA cycle builds on a knowledge of change in a structured manner, and then implements change on a broader scale with a higher chance of success.

This project follows the PDSA model by gradually introducing education in increments to one target population at time, refining education as needed, and implementing the change again. The "Plan" cycle involved establishing project objectives, predicting educational materials, content, and recipients, and determining distribution and data collection methods. The "Do" cycle involved developing and disseminating the educational materials to staff and patients, documenting problems and unexpected hurdles, and initiating data analysis via Epic software. The "Study" cycle consisted

of completing the data analysis, comparing data to predictions using descriptive statistics, and summarizing what was learned about this quality improvement project. The final "Act" cycle determined changes that need to be made to educational materials of staff and patients and setting the foundation for the next cycle. The PDSA model for this project can be visualized in Figure 1.

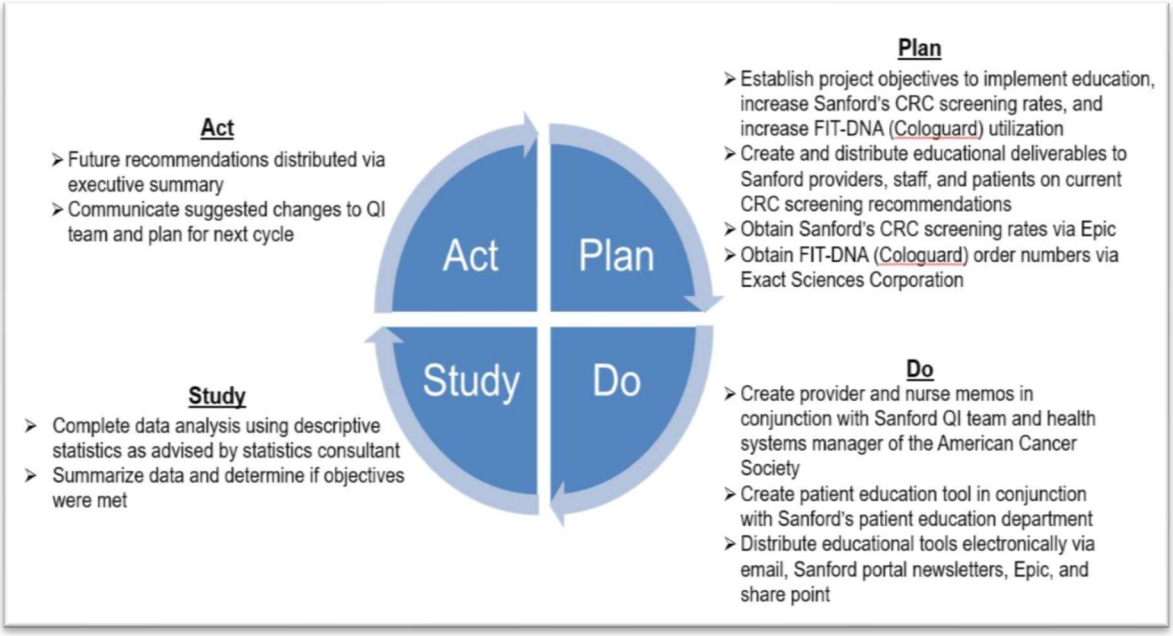

Figure 1. Theoretical Framework of Plan-Do-Study-Act

Congruence of the Project to the Organization's Strategic Plan/Goals

Healthy People is a national health promotion program, developed by the federal government, in effort to promote a healthier nation (CDC, 2014). Each decade, Healthy People launches a national health agenda, focused on nationwide priorities (Healthy People 2020, 2018). The priorities listed in the Healthy People 2020 agenda include objectives promoting evidence-based CRC screening (Healthy People 2020, 2018). These objectives stem from recommendations made by the USPSTF (CDC, 2017). Healthy People 2020 (2018) declares it a national goal to increase the proportion of adults who receive CRC screening and stresses the importance of effective communication between providers and patients stating, "Research shows patients cite a

recommendation from a health care provider as the most important reason for having cancer screening tests" (Cancer section, para. 3).

The N.D. Department of Health's Division of Cancer Prevention and Control aims to promote cancer awareness in the state of N.D. (N.D. Department of Health, 2015). The division works with the North Dakota Cancer Coalition (NDCC) to reduce the occurrence and impact of cancer for all North Dakotans (N.D. Department of Health, 2016). The NDCC contains a Screening Early Detection Work Group that lists the "80% by 2018" initiative as one of the workgroup goals (North Dakota Cancer Coalition, 2010). Additionally, the N.D. Department of Health, in conjunction with the American Cancer Society, developed the previously mentioned NDCCRT, which is another statewide coalition dedicated to decreasing the incidence of CRC by promoting approved prevention strategies.

In conclusion, the goal to increase screening and decrease the incidence of CRC is a national and state goal. Cancer prevention can decrease morbidity, mortality, and cost. Healthcare facilities, including Sanford Health, have joined the national and state effort by signing the "80% by 2018" pledge. Sanford has identified increasing CRC screening compliance as a priority and has taken measures to produce change. This project aims at increasing CRC prevention awareness and promoting approved CRC screening modalities to increase CRC screening rates and FIT-DNA utilization, which is congruent with national, state, and Sanford goals.

CHAPTER 3. PROJECT DESIGN

This quality improvement project evaluated the implementation of education provided to Sanford providers, staff, and patients regarding CRC screening options, with a focus on the newest screening option of FIT-DNA. The purpose of this project was to assess if the educational tools led to an increase in CRC screening rates within the Sanford Enterprise, and to evaluate if the addition of FIT-DNA was associated with increased screening compliance. The project design was developed using information gathered from the literature review, in conjunction with Sanford's Quality Improvement (QI) team that identified an enterprise-wide need. The identified problem was the lack of CRC screening among those at average risk, despite evidence supporting CRC screening and its known life-saving potential (CDC, 2017). The target population is providers and staff involved in the CRC screening ordering process and adults 50-75 years of age at average risk for CRC who receive care at Sanford Health. Educational tools were delivered by Sanford's QI team to all four Sanford regions. Rolling monthly data were collected on Sanford's CRC screening rates via Sanford's enterprise data analytics (EDA) team. The FIT-DNA data were collected to track ordering and completion rates from the Exact Sciences Corporation, which owns the patent on Cologuard. Pre- and post-education interventions were assessed to evaluate if a trend exists between education implementation, CRC screening rates, and utilization of FIT-DNA.

Project Implementation

Memos

Education was delivered to providers, nurses, medical assistants, and other medical staff via electronic memos. These memos were delivered at three and four months prior to the Epic ordering availability of FIT-DNA and its insurance coverage, both of which occurred in June 2017. The provider memo (Appendix A) was released in February 2017 via Sanford portal and email system with the target audience identified as primary care providers. The provider memo was created in

conjunction with the co-investigator, Sanford's QI team, and the health systems manager of the American Cancer Society. The one-page educational document provided current CRC screening recommendations, statistics regarding general CRC rates, as well as Sanford specific statistics that stated Sanford's goal of reaching 80% by 2018. The memo was tailored to target clinicians who screen patients for CRC and encourages these providers to "talk with your patients and give them options" (Appendix A).

The nurse memo was released in March 2017 via Sanford email with the target audience of nursing staff, medical assistants, and other healthcare workers who assist providers in CRC screening and ordering (Appendix B). The nurse memo was also created in conjunction with the co-investigator, Sanford's QI team, and the health systems manager of the American Cancer Society. The provider memo was edited to form the nurse memo, thus it included the same CRC screening recommendations and statistics. However, the nurse memo was tailored to target nurses, medical assistants, and other staff who assist in the CRC screening process. This one-page educational document addressed how nurses can assist in ordering CRC screening, how medical assistants can prep and pend CRC orders, and how other ancillary staff can help alert providers when screening and follow-up are needed.

Patient Education Tool

Education to patients was delivered via the patient education tool (Appendix C), which was approved by Sanford's patient education department in late September 2017 and distributed the following month to all Sanford regions via newsletters, emails, Epic software, and share point. The patient education tool was developed by the co-investigator, in conjunction with Sanford's patient education department, with the purpose of creating an informative, concise, and fluent chart that patients can review independently or with a provider or staff member. The one-page educational document included an introductory statement that encouraged patients to make choices about his or

her health. The tool then displays a chart explaining CRC options, adding a disclaimer that this chart refers to those patients at average risk for CRC. This education tool facilitates informed decision-making and patient autotomy when discussing and determining the best CRC screening option for the patient. The providers and staff guide and inform patients of screening options, yet ultimately, it will be the patients' choice as to which option is chosen.

The patient education tool was initially delivered via electronic newsletter to clinical informatics operations (CI-OPS) and leaders of frontline staff. The tool was dispersed via share point, which is Sanford's document management and storage system, targeted education emails, and Epic, where it can be accessed by providers under the "clinical practice guidelines." Providers are able to print the education tool or review it electronically with patients. In the near future, the patient education tool will be available in Epic in the after-visit summary (AVS), which is printed out and hand-delivered to the patient after every clinic visit. The education tool will automatically appear in the AVS of patients who are overdue for CRC screening.

Sample

The target population for the memos included primary providers, nurses, medical assistants, and other staff that assist in the ordering of CRC screening. The exact number of memo recipients was unable to be calculated because the chief medical officers of each region were given the memos to distribute to their staff, QI did not distribute the memo directly. However, it is estimated, using the known number of Sanford primary providers, that the memo reached at least 600 provider recipients.

The target population for the patient education tool includes men and women, ages 50-75, who are at average risk for CRC and receive care within the Sanford Enterprise. The exact sample size of patients screened was unable to be calculated because Epic software has a data-purging feature in order to keep the software running swiftly. The data was capable of being retrieved,

however, that was not considered a priority for the EDA team at that time. Although an exact number of patients screened was unable to be collected for this project, a running percent of screening rates was tallied monthly via the EDA team. The Exact Sciences Corporation tracked the number of entered orders for FIT-DNA as well as the number of tests completed within the Sanford Enterprise. Between the months of January 2017 and January 2018, there were 2,294 FIT-DNA stool tests ordered by Sanford providers, and the numbering of ordering providers totaled 386.

Protection of Human Subjects

When discussing ethics and the protection of human subjects, it is helpful to differentiate between clinical research and quality improvement. Clinical research involves "pursuing knowledge that is not known," and therefore risks are inherent (Melnyk &Fineout-Overholt, 2015, p. 523). Evidence-based quality improvement (EBQI) aims to "improve the processes or outcomes of the care being delivered (Melnyk & Fineout-Overholt, 2015, p. 609). EBQI is based on previously reviewed research and are associated with very low risks (Melnyk & Fineout-Overholt, 2015). Although this project is considered EBQI, it still requires IRB review "to assure participant safety and to enable the demonstration of how effective a given intervention is on outcomes within a particular setting" (Melnyk & Fineout-Overholt, 2015, p. 233).

While it is helpful to specifically classify whether a project is research or quality improvement, the most important factor is determining if the project is ethically appropriate (Melnyk & Fineout-Overholt, 2015). In order to assess appropriateness and safety, this quality improvement was submitted for IRB approval through NDSU's and Sanford's review board. Both Sanford and NDSU determined this quality improvement project was exempt from the IRB requirement because it did not directly involve the research of human subjects in terms of its regulatory definition of human research (Appendices E and F).

Risks and Benefits

Potential risks of this quality improvement project were low but included possible privacy and patient cost risks. During data collection and analysis, appropriate measures were taken to ensure that patient information was managed confidentially, and that patient privacy was upheld. This was achieved by Epic's data collection programming and Exact Sciences Corporation spreadsheets, where data was distributed numerically without any disclosure of patient information. In addition to patient privacy, cost was a potential risk because FIT-DNA is newly approved, and coverage initially varied depending on the patient's insurance. Cost must also be considered when the patient experiences a positive stool-based test and a follow-up colonoscopy is needed. Follow-up colonoscopies can be billed differently because it is considered a diagnostic test versus preventative screening. Overall, identified risks were low, therefore not implementing the project may have presented higher risks to patient health.

Potential benefits to the subjects included options for CRC screening that promoted autonomy and allowed the patient a choice in directing his or her plan of care. Providing options to patients assists in increasing screening compliance, which aids in detection, prevention, and health promotion. In addition to decreasing morbidity and mortality, increasing CRC screening compliance will decrease health care costs. Screening is considered more cost-effective than the treatment of cancer itself, which could include expensive oncological treatment plans (Allameh, Davari, & Emami, 2011). Increased screening compliance will also help meet quality measures that providers abide by in order to achieve the desired health outcomes of CRC prevention.

Data Collection

To track the CRC screening trends of the stated target population, a rolling 12-month percentage was calculated by the Sanford's EDA team. Data were collected in Epic via the health maintenance (HM) and reporting workbench software features. Health maintenance is an Epic

functionality that uses patient health history to prevent disease and promote health by tracking when patients are due for certain screenings, immunizations, etc. (Coronado et al., 2014). Health maintenance is a dynamic tool in relation to CRC screening because it is capable of reviewing the last type of CRC screening performed and adjusts due dates as indicated by the type of test performed or patient specific modifiers (Coronado et al., 2014). The HM function not only promotes CRC screening by informing providers and staff when CRC screening is due, it also helps in collecting accurate data on the percentage of patients who completed appropriate screening. To track the rate of completed CRC screening, data is pulled from the results field of HM, which is reviewed and addressed at every clinic visit.

In addition to the HM function, Epic also has a reporting workbench feature that uses templates that pull data from a specific registry to calculate reports. Many of these registries are pre-created in Epic to categorize and gather information about patients, with specified criteria, to manage chronic disease and promote wellness (Coronado et al., 2014). Reporting workbench is convenient for more real-time data and is helpful in reviewing current quality measure statuses (Coronado et al., 2014).

The Exact Sciences Corporation tracked the number of entered orders for FIT-DNA as well as the number of ordering providers within the Sanford Enterprise. The ordering process for FIT-DNA differs from other Sanford lab orders because Exact Sciences Corporation is responsible for running the stool-based test, as opposed to the hospital's lab. This is because Exact Sciences has "exclusive intellectual property protecting its noninvasive, molecular screening technology for the detection of colorectal cancer" (Exact Sciences, n.d.). Exact Sciences tracked Sanford-specific FIT-DNA data and reported this data to Sanford's QI team.

CHAPTER 4. EVALUATION

Evaluation of the project objectives was achieved via quantitative data analysis, where patterns and trends were identified. Data obtained from Sanford's QI department included regional and enterprise CRC screening rates of the identified population. Data from Exact Sciences included regional and enterprise ordering and completion rates of FIT-DNA for the identified population. Data were analyzed from January 2017 to January 2018, the year that Sanford set as a goal to reach an 80% screening rate. Within that 12-month period, the memos and patient education tool were implemented, and evaluation of CRC screening trends and FIT-DNA utilization were analyzed. Certain months will be examined more closely for potential changes in trends. These months include March 2017: one-month post-provider memo implementation, April 2017: one-month post-nurse memo implementation, July 2017: one-month post-widespread coverage of FIT-DNA and Epic ordering availability, and November 2017: one-month post-patient education tool implementation. Evaluation of CRC screening trends will be visualized via descriptive statistics to determine if a relationship exists between to pre- and post- educational implementation.

Through descriptive statistical analysis of the data, patterns and trends were compiled to draw conclusions from the results. Descriptive statistics is a type of analyses that summarizes, describes, and presents data about a sample (Conner & Johnson, 2017). Quantitative data, collected from Sanford and Exact Sciences Corporation, were analyzed using descriptive statistics to identify patterns and provide visual observations of the samples. While descriptive statistics is not typically used to reach conclusions about hypotheses, it can depict data in a meaningful way when analyzing quality improvement projects (Conner & Johnson, 2017). Descriptive statistics can also provide a foundation of preliminary data that can be used in future research and analyses (Conner & Johnson, 2017).

CHAPTER 5. RESULTS

The results of CRC screening rates are categorized by region, enterprise, and FIT-DNA specific data. Results are analyzed using descriptive statistics to determine if the stated objectives were met. The following tables, line, and bar graphs were utilized in this quality improvement project to depict trends and effectively summarize and describe data.

Objectives

Objective 1. Develop and implement educational materials regarding recommended CRC screening options to Sanford employees and patients

Three different educational materials were created to promote awareness of current CRC screening recommendations: the provider memo (Appendix A), the nurse memo (Appendix B), and the patient education tool (Appendix C). The provider and nurse memo were created in conjunction with the co-investigator, Sanford's QI team, and the health systems manager of the American Cancer Society. The provider memo was distributed via Sanford portal and email system, and it was also presented to Sanford's regional chairs at the scheduled "Tuesday Collateral" meeting where providers could ask questions in-person to Sanford's QI team regarding the memo's recommendations. The nurse memo was distributed via Sanford email with the target audience of nursing staff, medical assistants, and other healthcare workers who assist providers in CRC screening and ordering. The patient education tool was created by the co-investigator in conjunction with Sanford's patient education department and distributed via newsletters, email, Epic software, and share point. All educational materials were one-page in length and included concise, up-to-date CRC screening recommendations tailored to the target audience.

This objective was met with the assistance of Sanford's QI team, patient education department, and the health systems manager of the American Cancer Society. Collaboration with these three entities helped create and distribute the memos and patient education tool. Using the

previously described PDSA model, the tools can be revised and re-implemented as needed to achieve the corresponding objectives.

Objective 2. Increase Sanford's regional and enterprise CRC screening rates to a minimum of 80% by January 2018

Regional and enterprise data on monthly CRC screening rates were collected, entered into a spreadsheet, and converted into tables and graphs. Education tools were evaluated one-month post-implementation and compared to regional and enterprise CRC screening rates. Provider memos were distributed in February 2017, nurse memos were distributed in March 2017, and the patient education tool was distributed in October 2017. Regional data analysis displayed post-implementation variation in relation to CRC screening rates, with most regions demonstrating an increase in screening rates one month after educational materials were implemented. As an enterprise, CRC screening rates increased one month after each of the educational tools were implemented. See Table 2 for post-education implementation trends.

Table 2

Regional and Enterprise CRC Screening Rate Changes One-Month Post-Education Implementation

	Bemidji, M.N.	*Bismarck, N.D.*	*Fargo, N.D.*	*Sioux Falls, S.D.*	*Enterprise*
Provider memo (2/17-3/17)	No change	Increase (+1.6%)	Increase (+0.5%)	Increase (+0.2%)	Increase (+0.5%)
Nurse memo (3/17-4/17)	No change	Increase (+0.8%)	Increase (+0.2%)	No change	Increase (+0.2%)
Patient education tool (10/17-11/17)	Increase (+0.3%)	Increase (+0.5%)	Increase (+0.1%)	Increase (+0.1%)	Increase (+0.2%)

In addition to identifying patterns pre- and post- education, it is also important to consider pre- and post- widespread insurance coverage and Epic ordering availability of FIT-DNA in relation to CRC screening rates. FIT-DNA was covered by most insurance plans and was available for electronic order entry in June 2017. One month later, in July 2017, there were increases in CRC screening rates within all four regions and the enterprise. See Table 3 for trends.

Table 3

Regional and Enterprise CRC Screening Rate Changes One-Month Post FIT-DNA Insurance Coverage and Epic Ordering Availability

	Bemidji, M.N.	*Bismarck, N.D.*	*Fargo, N.D.*	*Sioux Falls, S.D.*	*Enterprise*
FIT-DNA insurance coverage and Epic ordering availability (6/17-7/17)	Increase (+0.6%)	Increase (+3.8%)	Increase (+2.5%)	Increase (+1.2%)	Increase (+2.0%)

Overall, the objective to reach a regional and enterprise CRC screening rate of 80% by January 2018 was not met. The Bismarck region displayed the greatest increase in screening rates from January 2017 To January 2018, where Bemidji showed the least increase. Although Bemidji displayed the least percentile increase over the 12-month period, the region's overall screening rate remains the highest of the four regions at 74.5%. Regional rates varied, however, all four regions and the enterprise displayed an increase in CRC screening rates. See Figure 2 for regional and enterprise screening rates from January 2017 and January 2018.

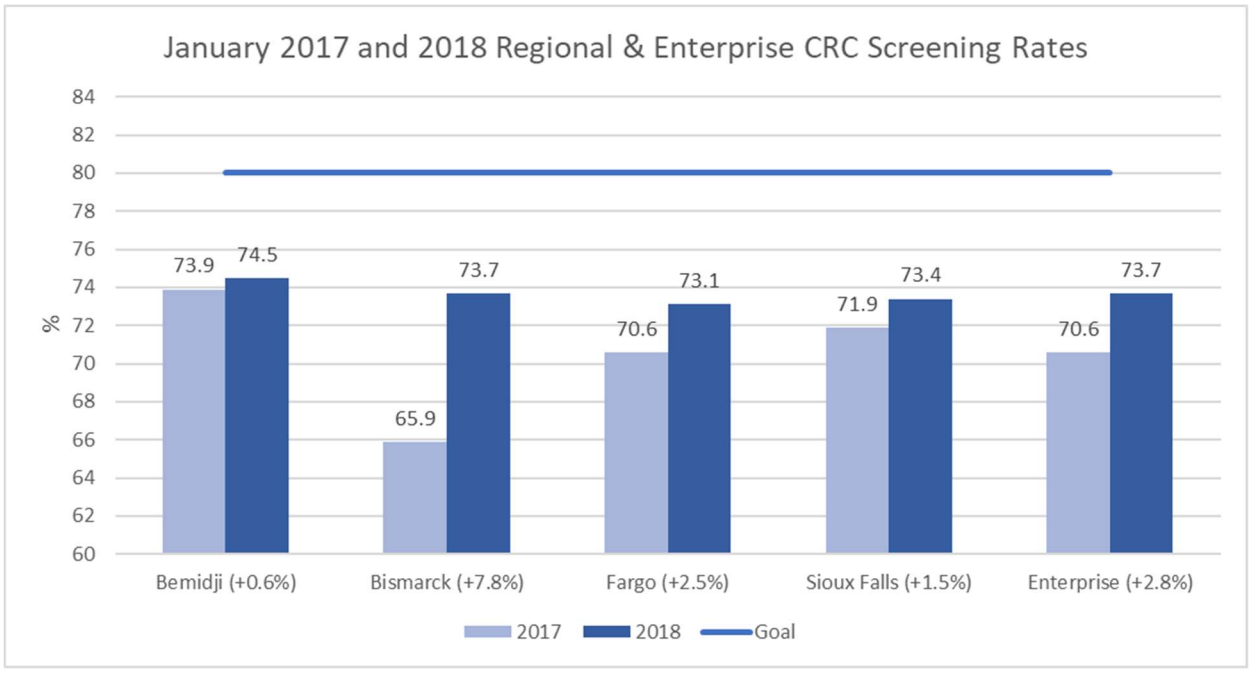

Figure 2. Sanford's Regional and Enterprise Screening Rates in January 2017 and 2018

Despite the objective not being met, trends show consistent increases in CRC screening. Steady increases in rates were noted from January 2017 to January 2018 in all four regions. Most regions experienced an increase in CRC screening rates post-memo distribution, while all regions experienced an increase in CRC screening rates post-patient education tool distribution. In addition to the education tools trending with increased CRC screening rates, the widespread insurance coverage and Epic ordering availability of FIT-DNA also trended with increased CRC screening rates. The data analysis reveals consistent increases in screening rates, however, none of the four regions reached this project's objective to attain an 80% screening goal by January 2018.

Although overall regional and enterprise screening rates did not reach 80% by 2018, there were 13 individual clinics that did reach the 80% screening goal. These clinics are listed in Table 4.

Table 4

Sanford Clinics that Reached 80% by 2018

Region	*Clinic*
Bemidji, MN	Bemidji Internal Medicine
Bismarck, ND	Bismarck Internal Medicine
	Dickinson Internal Medicine
	Mandan North
Fargo, ND	West Fargo Family Medicine
	Family Medicine Resident Clinic
	Fargo Internal Medicine
	Southpointe Internal Medicine
	Moorhead Internal Medicine
	Perham Internal Medicine
Sioux Falls, SD	Family Medicine 49th and Oxbow
	Sioux Falls Internal Medicine
	Women's Internal Medicine

Objective 3. Increase Sanford's utilization of FIT-DNA by January 2018

In order to evaluate the third objective, data were collected from Exact Sciences Corporation regarding Sanford's utilization of FIT-DNA. Numbers were collected from January 2017 to January 2018 depicting the amount of FIT-DNA orders placed, as well as the number of ordering providers. Data were entered into a spreadsheet and evaluated using descriptive statistics.

From January 2017 to January 2018, Sanford's FIT-DNA orders enterprise-wide increased from 21 total orders to 339 orders, which is equivalent to a 1,514% increase in 12 months. Provider memos were delivered in February of 2017, and in that month FIT-DNA orders totaled 14. One-

month post-provider memo, FIT-DNA orders increased to 139 in March of 2017, which is an 893% increase in one month. The nurse memo was delivered in March 2017, and one-month post-delivery, order numbers decreased to 121 in April 2017. Insurance coverage and Epic ordering availability occurred in June 2017, and numbers increased from 133 in June 2017 to 147 one-month later in July. The patient education tool was available in October 2017, when FIT-DNA orders reached an annual high of 362. One-month post implementation of the patient education tool, order numbers declined to 296 in November 2017. However, numbers increased again and reached 339 in January 2018. Enterprise FIT-DNA order trends can be visualized in Figure 3.

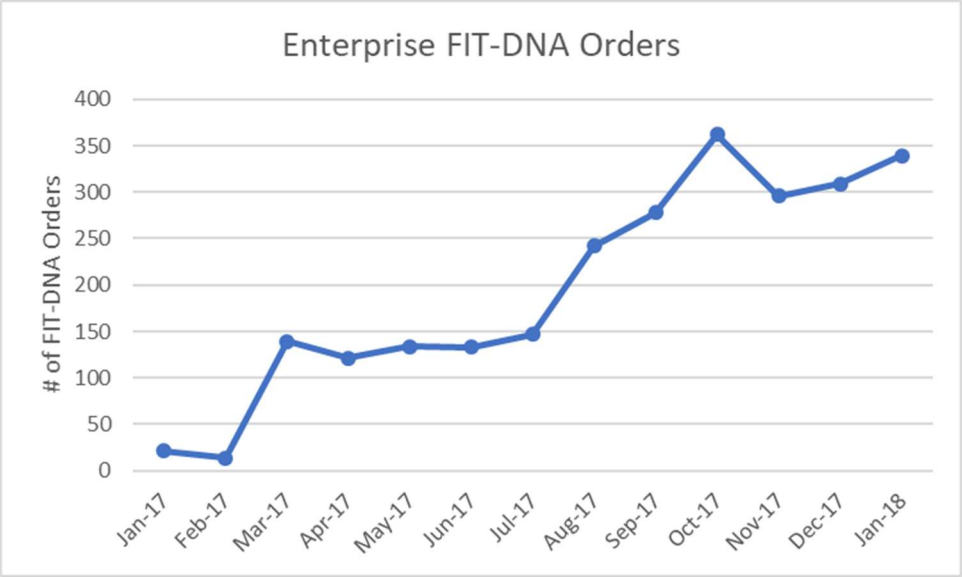

Figure 3. Enterprise FIT-DNA Order Trends

In addition to the total orders for FIT-DNA, Exact Sciences also collected data on the number of ordering providers within the Sanford system. In January 2017, there were 14 Sanford providers who ordered FIT-DNA compared to the 153 ordering providers 12 months later, showing a 993% increase. Provider memos were delivered in February 2017, and in that month, there were 12 providers who ordered FIT-DNA. One-month post-provider memo, 59 additional providers ordered FIT-DNA, equaling 71 total providers in March of 2017. These numbers demonstrated a

493% increase in providers who ordered FIT-DNA one month after education was implemented. The nurse memo was delivered in March 2017, and one-month post-delivery, ordering provider numbers decreased to 67 in April 2017. Insurance coverage and Epic ordering availability occurred in June 2017, and numbers increased from 77 ordering providers in June 2017 to 85 a month later in July. The patient education tool was available in October 2017, when the number of providers ordering FIT-DNA equaled 157. One-month post implementation of the patient education tool, ordering providers decreased to 136 in November 2017. However, the number of ordering providers increased again and reached 153 in January 2018. Trends depicting the number of enterprise providers who placed orders for FIT-DNA can be visualized in Figure 4.

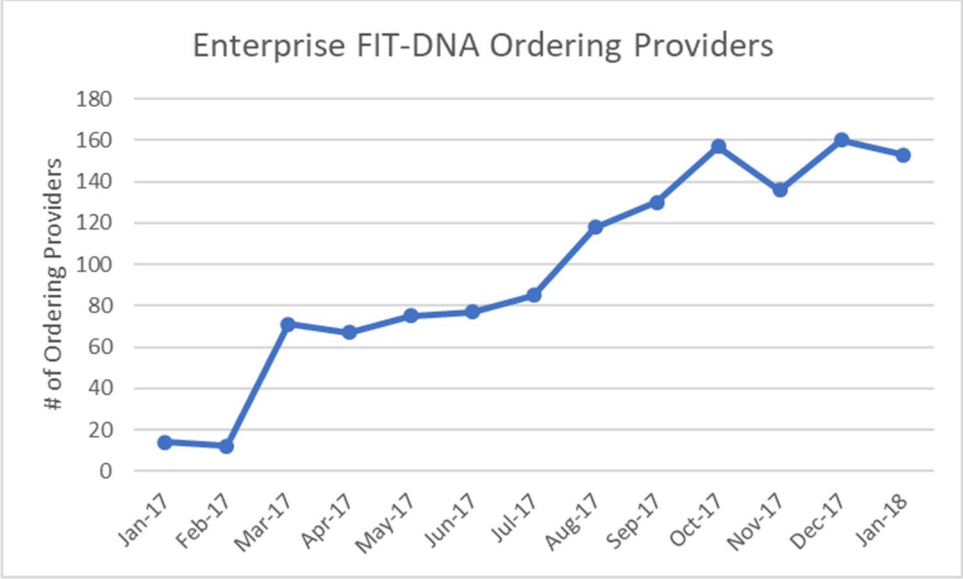

Figure 4. Sanford FIT-DNA Ordering Providers

While examining the trends of FIT-DNA in relation to the educational deliverables is useful, it is also meaningful to analyze the patterns of FIT-DNA utilization and overall CRC screening rates. Using a combination chart with a bar and line graph, the positive trend between increased FIT-DNA usage and Sanford's Enterprise CRC screening rates can be visualized. The primary axis

and line graph represent the number of FIT-DNA orders, while the secondary axis and bar graph represent the enterprise's CRC screening rates. See these trends in Figure 5.

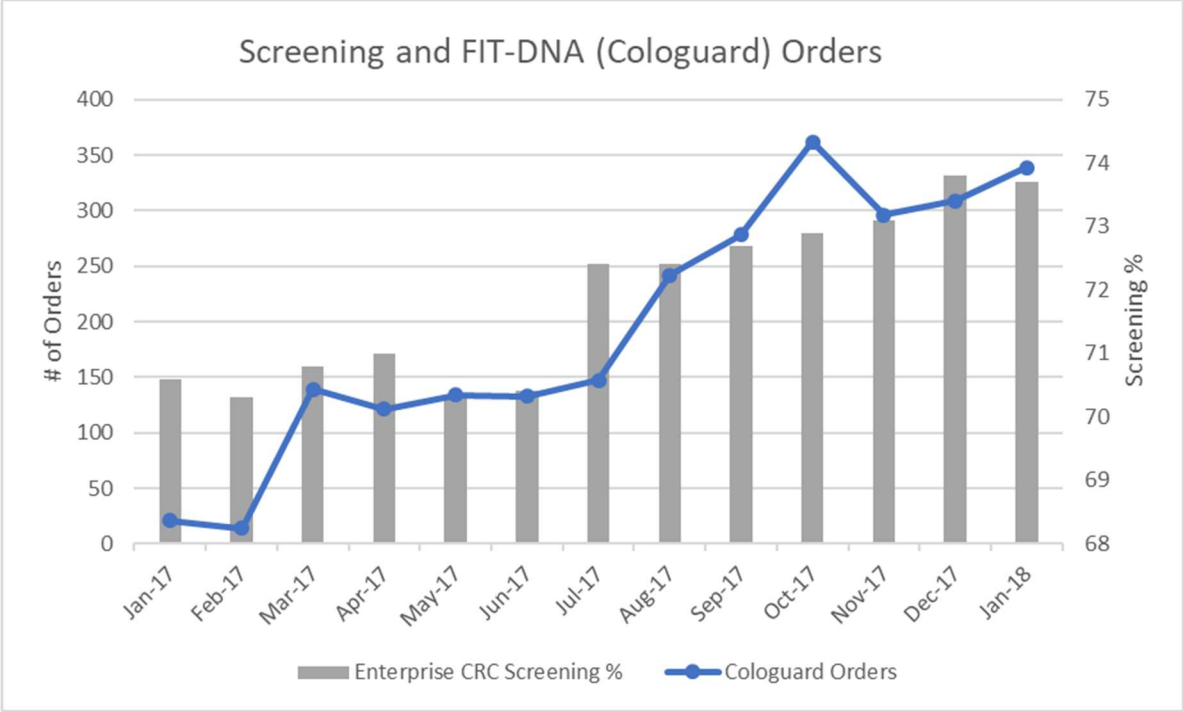

Figure 5. Screening and FIT-DNA Trends

The third objective of this quality improvement project was met because the data analysis shows the increased utilization of FIT-DNA throughout the Sanford Enterprise from January 2017 to January 2018. There was a notable increase in FIT-DNA orders one-month following the provider memo distribution where FIT-DNA orders increased by 125 from February to March, which was the largest incline in that 12-month period. The number of ordering providers also showed a notable increase from February to March 2017. In February there were 12 providers that ordered FIT-DNA, and this number increased to 71 one month later. This increase is the largest in the 12-month period and coincides with the same month that showed the largest increase of FIT-DNA orders. The upward trends between FIT-DNA orders and enterprise screening rates also demonstrate that the addition of another screening option can help improve overall screening rates.

CHAPTER 6. DISCUSSION AND RECOMMENDATIONS

Interpretation of Results

Overall, the implementation of educational materials to providers, staff, and patients, regarding current CRC recommendations, aided in increasing Sanford's CRC screening rates. Despite not meeting the 80% goal by January 2018, monthly trends indicate that screening rates and utilization of FIT-DNA are on the rise. As Sanford continues to strive for CRC prevention and early detection, it is hopeful that the 80% goal will be achieved within the remaining months of 2018.

Findings from this project show that provider education via the provider memo trended with an increase in CRC screening rates. Enterprise data trends indicated that one-month post-delivery of the provider memo, CRC screening rates increased by 0.5%. Regional data shows varying results one-month post-provider memo with Bemidji showing no change in CRC screening rates, Bismarck experiencing a 1.6% screening increase, while Fargo's rates decreased by 0.5 %, and Sioux Falls' rates increased by 0.2%. There is a visual association between the release of the provider memo and the increase in enterprise CRC screening rates the following month, despite varying regional data.

Although enterprise CRC screening rates trended slightly upward one-month post-provider education, FIT-DNA numbers showed a more notable upward trend. Total enterprise orders for FIT-DNA increased by 893% from February 2017 to March 2017. Not only did the orders of FIT-DNA increase, but the number of ordering providers also went up, showing a 493% increase one-month following the distribution of the provider memo. A more distinct trend can be seen between the release of the provider memo and the increase in orders and ordering providers of FIT-DNA.

Trends pre- and post- distribution of the nurse memo indicate that this memo may have had a similar influence in overall screening rates when compared to the provider memo. Enterprise data shows that one-month post-delivery of the nurse memo, CRC screening rates increased by 0.2%. Regional rates show varying results one-month post-nurse memo distribution with Bemidji showing

no change in CRC screening rates, Bismarck experiencing a 0.8% screening increase, Fargo's rates increasing by 0.2%, and Sioux Falls' rates remaining unchanged. There is a possible trend between the release of the nurse memo and the increase in enterprise CRC screening rates the following month, but again, regional data varies.

The FIT-DNA orders and ordering providers trended downward one-month post-nurse memo. FIT-DNA orders declined by 13% from February 2017 to March 2017. A similar downward trend is noted in the number of ordering providers. In March of 2017 the number of providers ordering FIT-DNA equaled 71, which then decreased to 67 one-month following the nurse memo distribution, demonstrating a 6% decrease. The nurse memo is does not trend with an increase of FIT-DNA orders, nor the number of providers ordering FIT-DNA. These trends may have resulted because a majority CRC screening orders are placed in Epic by the providers.

The patient education tool delivered in October 2017 trends with an increased enterprise screening rate one-month post-distribution. Enterprise screening rates increased by 0.2% from October to November 2017. Three out of the four regions also showed an increase one-month post patient education tool delivery with Bemidji rates increasing by 0.3%, Bismarck +0.5%, Sioux Falls +0.1%, while Fargo's screening rates declined by 0.1%. Although regional rates vary, a trend is visualized in the enterprise data analysis that shows the patient education tool may have been linked with increased CRC screening rates.

Findings from the FIT-DNA data analysis show a negative pattern one-month post-patient education tool. In October 2017, FIT-DNA orders equaled 362, which was the high for that 12-month period. Numbers then declined by 19%, to 296 orders, in the month of November. The number of providers ordering FIT-DNA also decreased one-month post-patient education tool distribution. In October, the number of providers ordering FIT-DNA totaled 157, and then dropped to 136 one month later, demonstrating a 13% decrease. December 2017 totaled 160 ordering

providers, which was 12-month high between January 2017 and January 2018. The patient education tool does not trend with an increase in FIT-DNA orders, nor ordering providers, one-month post-tool distribution. These trends may have occurred because the one-month evaluation period was an insufficient turn-around time for patients to contemplate the tool and make a screening decision.

Overall, the provider and nurse memos showed an upward trend with the enterprise CRC rates one-month post distribution. The number FIT-DNA orders and ordering providers increased one month following the provider memo release, however, the orders and ordering providers decreased one month after the nurse memo's release. The patient education tool data analysis showed an increase enterprise screening rate one-month post-distribution, while FIT-DNA orders and ordering providers declined. All three forms of education trended with the increase in enterprise CRC screening rates one-month post-implementation. While only the provider memo trended with an increase in FIT-DNA orders and number of FIT-DNA ordering providers.

When evaluating the 12-month period of January 2017 (pre-education implementation) to January 2018 (post-education implementation), one can appreciate the consistent increases in CRC screening throughout the regions and enterprise. The 12-month data and percentages can be visualized in Figure 2. It is also important to note the association between the increase in FIT-DNA utilization and the escalation in CRC screening rates in Figure 5. While it is useful to evaluate the effectiveness of individual tools, the 12-month data and graphs provide a more comprehensive picture regarding the effectiveness of pre- and post- education implementation.

Limitations

There are several limitations of this quality improvement project. Statistical limitations include the unknown sample sizes of staff who received the memos, as well as the unknown sample size of patients who received the educational tool. The data collected by Sanford's Epic system was

not programmed to hold a specific sample size of those who were screened for CRC, rather the system was programmed to obtain a rolling 12-month percentage. Assumptions can be made about the sample sizes, however, this would not lead to statistically meaningful results.

In addition to the unknown sample sizes, there were limitations on the type of data collected. Overall CRC screening percentages were obtained from Sanford and Exact Sciences provided ordering and completion numbers for FIT-DNA, but data on other recommended screening modalities, such as colonoscopy, FIT, CT colonography, etc., were unable to be obtained. This limits the ability to directly compare which CRC screening modalities were commonly chosen.

Another limitation of this project was the inability to directly evaluate the helpfulness of the educational materials from staff and patients. This form of evaluation was avoided due to Sanford's concern for over-surveying the staff and patients. The helpfulness of the education tool created for patients was also not able to be directly evaluated because there were no tracking methods in place to determine which patients received the tool.

This project was also under a time limitation, which lead to a limited ability to cycle through the previously described PDSA model to implement any educational changes. However, a foundation of knowledge regarding efforts to increase CRC screening compliance was achieved, and future work could build off of these initial findings. Overall, the constraints of this quality improvement project lead to statistical and evaluative limitations, however, the results and patterns remain useful as these findings have potential to influence future clinical practice.

Recommendations for Implementation Sites

It is imperative that healthcare providers remain current on evidence-based practices and maintain clinical competencies in order to improve health outcomes (Militello, Gance-Cleveland, Aldrich, & Kamal, 2014). With constantly evolving literature and guidelines, providers and healthcare staff benefit from organized, concise educational materials (Militello et al., 2014).

Memos, or memorandums, can be an effective mechanism for delivering education as they are informational, brief, and can be delivered electronically to reach large populations (Purdue University, 2018). Sanford utilized provider and nurse memos to deliver concise, up-to-date information on CRC screening recommendations, including the newest screening test, FIT-DNA. The memos were sent electronically to reach a large population of Sanford employees that span across three states. Overall, analysis of data shows that both provider and nurse memos trended with an increase in CRC screening and helped achieve the desired outcome of increased CRC screening awareness and compliance.

The provision of patient education is invaluable because it "improves patient satisfaction and outcomes, improves quality of care, and lowers healthcare costs" (Shipman, Lake, Van Der Volgen, & Doman, 2016, p. 154). There is increasing emphasis on accountable healthcare, and because patient education can affect reimbursement from Centers for Medicare and Medicaid Services (CMS), clinicians are held liable for delivering patient education (Shipman et al., 2016). To assist providers and healthcare staff in this task, accessible and up-to-date patient education material should be readily available (Shipman et al., 2016). Sanford's electronic, printable patient education tool was meant to do just that. It is a one-page informational deliverable that includes a concise chart for patients to review screening options.

In addition to the nurse and provider memo, analysis of data shows that the patient education tool also trends with an increase in enterprise screening rates. Regional data varied, but a majority of the regions showed a positive pattern between increased CRC screening rates one-month post-distribution of the patient education tool. The FIT-DNA orders and ordering providers declined one-month post-delivery but then continued to climb over the next two months. The patient education tool may not have had a considerable influence on FIT-DNA orders, but it is difficult to conclude since data to track the number of patients the tool was delivered to is unavailable. Currently,

Sanford is making the patient education tool available in the patient's AVS, and this could have more impact on CRC screening rates. The education tool has only been available since October 2017, therefore, more time may help clarify its usefulness. Recommendations are to revise and re-implement educational tools as needed to achieve the 80% screening goal.

Implications for Practice

Cancer has a major impact on society, affecting millions of patients and families across the nation (National Cancer Institute, 2017). Cancer can be lethal, and it is important to recognize that prevention is considered the best way to fight cancer (CDC, 2017). Colorectal cancer is largely preventable, yet it is one of the leading causes of cancer deaths in the U.S. (Cooper & Gelb, 2016). Providers in primary care, who are routinely involved in health maintenance and screening, are on the front lines of cancer prevention. Primary care providers can save the lives of many who are not being appropriately screened for CRC. Increasing screening compliance may depend on the delivery of education and offering patients options. Educating providers, staff, and patients on up-to-date CRC screening recommendations and options can improve CRC screening rates and minimize negative health outcomes (Muliira et al., 2016).

Barriers should be considered when discussing CRC screening options with patients. Barriers can include, but are not limited to, test preparations, invasiveness, possible complications, handling of stool, frequency, and cost. These possible barriers can prevent patients from getting screened, therefore it is important to provide education on the different forms of screening and allow patients choices, keeping in mind that the best screening is the one that gets done (USPSTF, 2016). By informing providers, healthcare staff, and patients on CRC screening recommendations, with the new option of FIT-DNA, CRC screening rates have the potential to reach the desired goal of 80%.

This quality improvement project concludes that education to providers, staff, and patients is an important part of achieving screening goals. Sanford continues to use the patient education tool that is available in Epic and is currently being added to the AVS of patients who are overdue for screening. The original education tool (Appendix D) was distributed to the NDCCRT and NDCC to be used as an educational tool by other healthcare facilities who wish to utilize it. Overall, the project's patient education tools were adopted by Sanford and the health systems manager of the American Cancer Society of the Great West Division, who distributed the tool to the NDCCRT and NDCC.

Dissemination

Results of this quality improvement project will be shared with Sanford's QI team via an executive summary (Appendix G). The findings will also be presented at a poster presentation this spring at North Dakota State University. The original patient education tool (Appendix F) was emailed to the health systems manager of the American Cancer Society, who then distributed the tool to the previously mentioned formal state groups: the NDCCRT and NDCC. A summarized format of this project will also be submitted to at least three journals. A three-minute video will also be submitted to NDSU's graduate school summarizing this quality improvement project for a lay audience. Further dissemination may be completed upon Sanford's request.

Implications for Future Research

The FIT-DNA test is the newest addition to the recommended CRC screening modalities, as it was approved in 2016 by the USPSTF. As previously described in the literature review, databases yield minimal results when this product is searched due to its novel, yet clinically tested and approved, status. Because FIT-DNA is new, and national screening rates remain subpar, it would be ideal if additional research were completed regarding the relationship between the additional choice of FIT-DNA and its effect on CRC screening rates. If offering patients more options is associated

with increased screening compliance, then could offering patients additional options, such as FIT-DNA, increase screening rates? More research is needed to answer that question. A reasonable place to start is providing education to providers, staff, and patients on current recommendations, and evaluating if that education was effective. Memos and patient education tools were utilized in this study, however, further studies on effective education modalities regarding CRC screening compliance would be beneficial, particularly since a new screening modality was recently added as a viable screening option.

Applications to Other DNP Roles

The DNP profession builds off a foundation of evidence-based practice, quality improvement, and leadership (AACN, 2017). The DNP's role is to provide scientific-based care to promote health, prevent disease, and achieve quality outcomes (AACN, 2017). This quality improvement project generated new findings associated with educational tools distributed to providers, staff, and patients on up-to-date CRC screening prevention. This project also provided information regarding the relationship between the addition of FIT-DNA and overall CRC screening rates. The DNP can utilize this information and apply it to clinical practice by offering preventative, evidence-based screening measures to appropriate patient populations.

Conclusion

Colorectal cancer is one of the leading causes of cancer fatalities in the U.S., yet this type of cancer is considered highly preventable through the appropriate screening processes (CDC, 2016). Despite the efficacy of CRC screening, many eligible individuals are not being screened. In effort to improve screening compliance, providers should discuss possible screening barriers and offer patients choices, including the newly approved screening test, FIT-DNA. Discussing all forms of screening options with patients is important because compliance may depend on "raising awareness

that colonoscopy is not synonymous with colorectal cancer screening" (Cooper & Gelb, 2016, p. 994).

In addition to educating patients, keeping providers and other healthcare staff up-to-date with current recommendations can help disseminate the message that any screening is considered good screening for those at average risk for CRC. Providers and healthcare staff can help increase CRC screening rates by "offering patients the range of recommended screening options and should recommend colorectal cancer screening opportunistically, when patients visit for any reason." (Cooper & Gelb, 2016, p. 994). The addition of FIT-DNA adds another option for CRC screening, and it is predicted that offering options to patients will have the greatest effect on reducing CRC deaths (USPSTF, 2016). Educating providers, nurses, other medical staff, and patients regarding up-to-date CRC screening modalities and offering patients choices can improve screening rates and reduce CRC morbidity and mortality (USPSTF, 2016).

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APPENDIX A. PROVIDER MEMO

The American Cancer Society estimates that 135,430 people will develop colorectal cancer in 2017 and that approximately 50,260 will die of the disease. Colorectal cancer is very curable when detected early, but less than half of all cases are detected early enough. Screening is recommended for all individuals between the ages of 50 and 75 years.[1]

Screening Recommendations:

- Colonoscopy
  - Screening interval: every 10 years
  - **A Primary Care Provider recommendation is the number one indicator for whether or not a patient will have a colonoscopy.**[2-3]
- Fecal Immunochemical Test (FIT)
  - Recommended for average-risk patients (See New NCCRT Brief on Identifying High Risk Families in Practice)
  - Screening interval: annual
  - Positive tests should be followed by a colonoscopy
  - Obtaining stool for guaiac testing from a digital rectal examination is no longer recommended.
- FIT DNA Test (Cologuard)
  - Detection test for people declining a colonoscopy
  - Screening internal: every three years
  - Positive tests should be followed by a colonoscopy
  - Cologuard is **not** covered by all insurances currently. Please ask your patients to call their insurance company to see if Cologuard is the right test for them.
- Flexible sigmoidoscopy and FIT
  - Screening interval: flexible sigmoidoscopy every 5 years and FIT annually

Talk with your patients and give them options. In a recent study, patients offered only colonoscopy had much lower screening rates than those who were offered FIT or their choice of either test. Based on those findings, options should be offered so that some type of screening is completed.[4]

Work as a team! Your nurses can help order colonoscopy and FIT colorectal cancer screening tests per protocol.

The American Cancer Society and the National Colorectal Cancer Roundtable have endorsed a goal of 80% of individuals over 50 being screened by 2018. Sanford has signed on to the 80% by 2018 national goal. With partners working together toward this shared goal it is estimated that **203,000 deaths will be prevented** by the year 2030.

Sanford is inching closer to the 80% goal with an enterprise screening rate of 70.9%. The Bemidji region leads with 73.9% of eligible patients screened, followed by Sanford Sioux Falls at 71.9%, Fargo at 70.8%, and Bismarck at 65.9%. These numbers are inspiring, and our goal is within our reach. Sanford's mission is dedicated to health and healing, and advocating for colorectal cancer screening promotes a culture of improving the human condition and the health of its community members.

We will need the help of each one of you to be successful in this endeavor. An excellent educational piece regarding FIT testing you can use with your patients is available at FIT Information_Colon Cancer Alliance. You can also view an 8 minute video about talking with patients about colorectal cancer screenings at Sanford CRC Screening Video.

1. Colorectal Cancer Facts & Figured. American Cancer Society Website. http://www.cancer.org/research/cancerfactsstatistics/colorectal-cancer-facts-figures Published 2015. Accessed November 11, 2015.
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APPENDIX B. NURSE MEMO

The American Cancer Society estimates that 135,430 people will develop colorectal cancer in 2017 and that approximately 50,260 will die of the disease. Colorectal cancer is very curable when detected early, but less than half of all cases are detected early enough. Screening is recommended for all individuals between the ages of 50 and 75 years.[1]

Screening Recommendations:

- Colonoscopy
  - Screening interval: every 10 years
  - **We have a nursing protocol for ordering a screening colonoscopy! The correct order is included in the health maintenance BPA.**
- Fecal Immunochemical Test (FIT)
  - Recommended for average-risk patients (See New NCCRT Brief on Identifying High Risk Families in Practice)
  - Screening interval: annual
  - **We have a nursing protocol for ordering a FIT test!**
  - Positive tests should be followed by a colonoscopy
  - Obtaining stool for guaiac testing from a digital rectal examination is no longer recommended.
- FIT DNA Test (Cologuard)
  - Detection test for people declining a colonoscopy
  - Screening internal: every three years
  - Positive tests should be followed by a colonoscopy
  - Cologuard is **not** covered by all insurances currently. Please ask your patients to call their insurance company to see if Cologuard is the right test for them.
- Flexible sigmoidoscopy and FIT
  - Screening interval: flexible sigmoidoscopy every 5 years and FIT annually

Work as a team!

- Nurses can make a huge difference in the lives of patients by helping providers order colon cancer screening tests via the *Sanford Adult Wellness Screening Protocol Orders* and the *Nursing Protocol Order – Colorectal Cancer Screening – Fecal Immunochemical Test (FIT)*.
- Medical assistants can prep and pend CRC Screening testing for the providers to sign.
- Other members of the care team also play a vital role in recognizing the need for screening by alerting the provider of the need for follow-up.

Promoting patient autonomy and offering choices is important. Studies have shown that offering options to patients leads to increased screening compliance.[2] As you offer screening choices, keep in mind that the best screening is the one that gets done. Your help can save lives, and your unique relationship with patients is an invaluable partnership that is vital in promoting health and preventing disease.

The American Cancer Society and the National Colorectal Cancer Roundtable have endorsed a goal of 80% of individuals over 50 being screened by 2018. Sanford has signed on to the 80% by 2018 national goal. With partners working together toward this shared goal, it is estimated that **203,000 deaths will be prevented** by the year 2030.

The Fargo Region is inching closer to the 80% goal with a rate of 70.8%. Sanford's mission is dedicated to health and healing, and advocating for colorectal cancer screening promotes a culture of improving the human condition and the health of its community members. We will need the help of each one of you to be successful in this endeavor. An excellent educational piece regarding FIT testing you can use with your patients is available at FIT Information_Colon Cancer Alliance. You can also view an 8 minute video about talking with patients about colorectal cancer screenings at Sanford CRC Screening Video.

1. Colorectal Cancer Facts & Figured. American Cancer Society Website. http://www.cancer.org/research/cancerfactsstatistics/colorectal-cancer-facts-figures. Published 2015. Accessed November 11, 2015.
2. Herrick LM, Ireland, J. Colorectal cancer prevention and detection. *South Dakota Medicine*. 2015; 91.

APPENDIX C. SANFORD PATIENT EDUCATION TOOL

Choosing which colon and rectal cancer screening option is right for you

SANFORD HEALTH

You can make choices about your health. Screening for colon and rectal cancer is recommended for everyone between the ages of 50 to 75. Choosing to do screening can save your life. Your age and other health factors affect when and how you should be screened.

Use this tool to talk to your doctor about 3 screening options. Each column below outlines 1 way to do screening. Compare each option to choose which screening method is best for you. Remember, the **best** screening option is the one that gets done!

Note: if you have a history of colon cancer or bowel disease, or have a close relative with colon cancer or polyps, a colonoscopy may be the best choice for you.

	FIT	Cologuard FIT-DNA	Colonoscopy
What is it?	Fecal Immunochemical Test: Stool is checked for blood (not seen by the naked eye) by taking a sample and mailing it in.	Stool is checked for cancer markers and blood (not seen by the naked eye) by taking a sample and mailing it in.	A lighted scope with a camera is used to look at the colon and rectum. This finds tissues and cells that are not normal.
Where is it done?	You collect a sample at home and return test kit to lab or mail it back (often pre-paid postage is included).	A test kit will be mailed to your home. You will collect a sample and mail the test kit back (address label and postage stamp included).	Your provider will give this test at the hospital in a procedure room. Medicines will be given to you to provide comfort.
How often?	Completed every 1-year if normal *If test is not normal, you will need a colonoscopy	Completed every 3-years if normal *If test is not normal, you will need a colonoscopy	Completed every 10-years if normal *May include a biopsy or polyp removal if needed
How do I get ready?	No preparation or diet restrictions required	No preparation or diet restrictions required	Requires fasting and a cleansing of the colon with a laxative
What is the cost?	Low Cost – check with your insurance (often covered)	Variable cost – Check with insurance (sometimes covered)	Higher cost – check with insurance (often covered if qualified)

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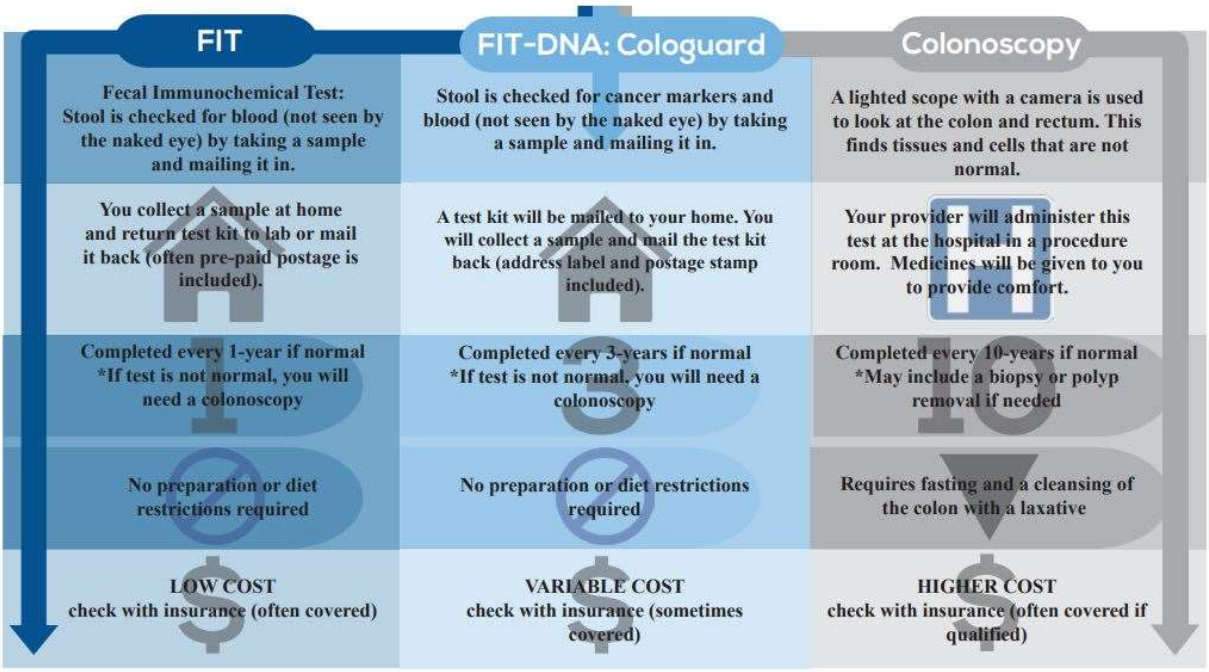
APPENDIX D. ORINGINAL PATIENT EDUCATION TOOL

You get to make choices about your health. Screening for colon and rectal cancer can save your life. Age and other risk factors determine when you should get screened. There are many types of screening tests. Below are 3 options. Use this tool to talk with your provider.

Screening is recommended for men and women, ages 50-75, at <u>average</u> risk for colon cancer. This means that if you have
(a) personal history of colon cancer or bowel disease or
(b) a close relative with a history of colon cancer or polyps, then stop here. Talk with your provider, a colonoscopy may be the best option for you.

If the (a) and (b) do not apply to you, then follow the map below to decide which option is for you.
Remember, the best screening is the one that gets done!



APPENDIX E. SANFORD IRB WAIVER

SANFORD HEALTH

NOT HUMAN RESEARCH

August 30, 2017

Dear Sarah Hanish:

The IRB reviewed the following submission:

Type of Review:	Initial Study via Non-Committee Review
Title of Study:	Colorectal cancer: Improving screening compliance with the utilization of Cologuard
Investigator:	Sarah Hanish
IRB ID:	STUDY00001089
Documents this review:	• Sarah Hanish, Category: IRB Protocol;

The IRB determined, on 08/29/2017, that the proposed activity is not human research. Sanford IRB review and approval is not required.

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are being considered and there are questions about whether IRB review is needed, please submit a study modification to the IRB for a determination. You can create a modification by clicking **Create Modification / CR** within the study.

For questions please contact the IRB Office: eIRB@sanfordhealth.org.

APPENDIX F. NDSU IRB WAIVER

NDSU NORTH DAKOTA STATE UNIVERSITY

September 26, 2017

Kara Falk
Nursing

Re: Your submission to the IRB: "Colorectal Cancer: Improving Screening Compliance with the Utilization of Cologuard"

Research Team Members: Sarah Hanish

Thank you for your inquiry regarding your project. At this time, the IRB office has determined that the above-referenced protocol does not require Institutional Review Board approval or certification of exempt status because it does not fit the regulatory definition of 'research involving human subjects'.

Dept. of Health & Human Services regulations governing human subjects research (45CFR46, Protection of Human Subjects), defines 'research' as "…a systematic investigation, research development, testing and evaluation, designed to contribute to generalizable knowledge." These regulations also define a 'human subject' as "…a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

It was determined that your project does not require IRB approval (or a determination of exemption). The IRB has determined that the project does not meet the regulatory definitions of "research" involving "human subjects".

We appreciate your intention to abide by NDSU IRB policies and procedures, and thank you for your patience as the IRB Office has reviewed your study. Best wishes for a successful project!

Sincerely,

Kristy Shirley

Digitally signed by Kristy Shirley
DN: cn=Kristy Shirley, o=NDSU, ou=Institutional Review Board, email=kristy.shirley@ndsu.edu, c=US
Date: 2017.09.26 11:18:11 -05'00'

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 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb
Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

APPENDIX G. EXECUTIVE SUMMARY

COLORECTAL CANCER

SCREENING • COMPLIANCE

Project Summary

Colorectal (CRC) is the second leading cause of cancer fatalities in the United States, yet it is considered a highly preventable disease with the use of appropriate screening processes (CDC, 2016). Despite the efficacy of CRC screening, national and state screening rates remain substantially low. This project focused on creating and distributing educational materials to Sanford's healthcare workers and patients on current CRC screening recommendations, including the recently-approved stool-based screening, FIT-DNA (Cologuard), in effort to increase CRC screening rates.

Background

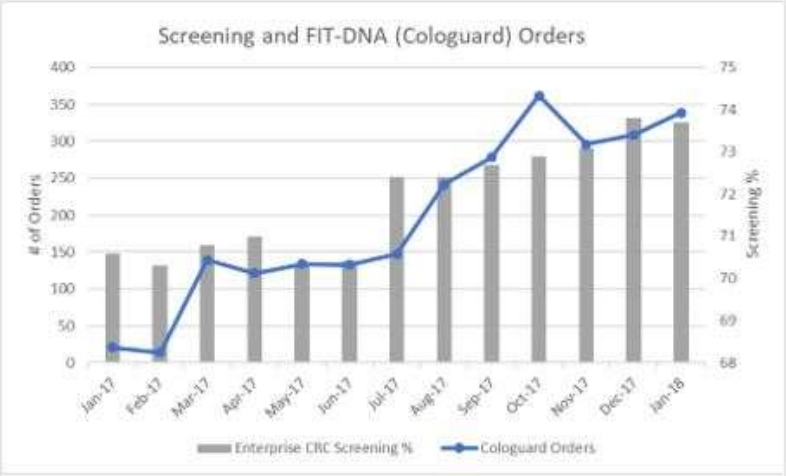
Due to subpar CRC screening rates, Sanford Health signed a pledge, put forth by the North Dakota Colorectal Cancer Roundtable, to reach a CRC screening goal of "80% by 2018." Studies have shown that providing patients with screening choices can increase screening compliance (USPSTF, 2016). FIT-DNA is a stool-based test that was added to the national guidelines as a recommended form of screening. Because of its determined efficacy, FIT-DNA obtained widespread insurance coverage in June 2017. Around the same timeframe, Sanford added FIT-DNA to the Epic system and made it readily available for electronic order entry. Because of recent additions to CRC screening recommendations and the historical subpar screening rates, education was deemed necessary to assure healthcare workers were up-to-date on CRC screening recommendations, and to assure patients were making informed-decisions.

Process

Education was delivered to healthcare staff via electronic provider and nurse memos. Patient education was addressed with an electronic, printable patient education tool that could be reviewed independently, or with a provider or nurse. Data were then collected over a 12-month period on regional and enterprise screening rates, along with FIT-DNA order numbers. The relationship between pre- and post- education implementation, CRC screening rates, and FIT-DNA utilization was examined using descriptive statistics.

Findings & Conclusions

Although there were statistical and evaluative limitations of the project, findings showed that educational tools trended with increases in CRC screening rates and FIT-DNA utilization. There was also a positive pattern between the addition of the FIT-DNA and increased enterprise CRC screening rates. Based on the results of the evaluation, education delivered to healthcare workers and patients on current screening recommendations, with an emphasis on offering patients options, can improve CRC screening compliance. See image below to visualize the trends between FIT-DNA implementation and Sanford Enterprise screening rates.



Recommendations for Further Action

To improve screening compliance for those at average risk for CRC:

- Providers should discuss possible screening barriers and offer patients choices, including the newly approved screening test FIT-DNA.
- Discussing all forms of screening options with patients is important because compliance may depend on "raising awareness that colonoscopy is not synonymous with colorectal cancer screening" (Cooper & Gelb, 2016, p. 994).
- Keeping providers and other healthcare staff up-to-date with current recommendations can help disseminate the message that the best screening, for those at average risk for CRC, is the one that gets done.
- Revise and re-implement educational materials as needed to achieve the desired health outcome of reaching an 80% CRC screening rate by 2018. Sanford's screening improvement from January 2017 to January 2018 is shown in the figure below.