The Effect of a Patient Navigator Strategy on Colorectal Cancer Screening Completion in a Women’s Health Clinic

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Martha Rosenthal, Student
Dr. Lynne Jensen, Advisor
DNP Final Project Report

The Effect of a Patient Navigator Strategy on Colorectal Cancer Screening Completion in a Women’s Health Clinic

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Spring 2019

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EFFECT OF A PATIENT NAVIGATOR ON CRC SCREENING

Dedication

I dedicate my work to my grandmother Renee. She passed away my last semester. I will forever remember her grace, kindness, humbleness, hard work ethic, and loyalty to her family. She has taught me valuable life lessons that I will forever try to embody in my personal and professional life.
EFFECT OF A PATIENT NAVIGATOR ON CRC SCREENING

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I would like to thank multiple friends, family, and mentors I have known and met along this journey. To my family and friends, especially my mother, who know me best and have been there whenever I needed them, they offered endless support, love, and laughs to get me through. To my coworkers and fellow students in this program, for always understanding and offering support when needed, it goes a very long way. Finally, I would like to acknowledge my professors and colleagues in this program. They have gone out of their way to help and prepare me during this education journey. Special thanks to Dr. Beth Woods, Dr. Angie Grubbs, Dr. Elizabeth Tovar, and Dr. Judi Daniels for setting such good examples as teachers and providers during my clinical time and to my committee members Dr. Julianne Ossege and Dr. Chris Yost.

To, Dr. Lynne Jensen, who played a vital role in where I am today. I would like to express my sincere gratitude to her as my advisor, committee chair, preceptor, and mentor. I will forever be grateful and look up to her as I practice in my future career. Thank you to her for her countless encouragement, compassion, tough love, and support. She was instrumental in where I am today. Her dedication to the betterment of others and myself is inspirational.
# EFFECT OF A PATIENT NAVIGATOR ON CRC SCREENING

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Abstract

BACKGROUND: Colorectal cancer is the second leading cause of cancer related death in the US. Kentucky has one of the highest rates of the disease. Approximately 1/3 of the population has not completed screening for colon cancer as recommended by guidelines. Patient navigation is a strategy proposed to increase completion of screening in the primary care setting.

PURPOSE: The purpose of this quality improvement pilot project was to provide preliminary data on the impact of a patient navigation strategy to improve colon cancer screening completion in low risk individuals.

METHODS: Colon cancer screening completion using Colonoscopy or Cologuard testing was compared between 30 navigated patients and 30 routine care patients in a women’s health primary care clinic. The prevalence and prevalence odds ratios were computed to measure the association between patient navigation and the project outcome measures. The barriers to non-completion of screening were also assessed. The overall results were compared to findings in the New Hampshire Colorectal Cancer Screening Program PN protocol endorsed by the CDC.

RESULTS: Patients in the PN intervention group were 5 times more likely to complete colon cancer screening than control patients ($P = .021$) and 2.7 more likely to also have had a Colonoscopy date scheduled ($P = .015$). In addition, 55.5% of navigated patients completed screening after receiving mailed screening enrollment forms versus 23.8% completion whose enrollment was on an online ordering portal alone.

CONCLUSION: Patient navigation can be used as strategy for increasing colon cancer rates in low risk individuals. Other contributors to increases in screening included having designated personnel for enrollment processes, offering a choice in screening test, mailed reminders for enrollment in screening, and access to an online ordering portal.
Introduction

Globally, colorectal cancer (CRC) is the third most common cancer in the world (American Cancer Society, 2017). CRC is the second leading cause of cancer related death in the United States (U.S) among men and women, with 140,788 new cases diagnosed in 2015 (U.S. Cancer Statistics Working Group, 2014). Screening can detect colon cancer earlier when treatment is more successful, decreasing the incidence of disease and CRC mortality (American Cancer Society, 2019). Of those individuals considered at average-risk in 2014, only 65.7% were reported to be up to date with screening as recommended (CDC, 2014 & CDC, 2018). Multiple barriers to screening exist that prevent proper screening completion; these include health disparities, healthcare system barriers, patient beliefs about screening, and access to care (Ely et al, 2016). Patient navigation (PN) is a suggested strategy supported by the Center for Disease Control and Prevention (CDC) that can help individuals overcome these barriers and complete CRC screening (Rice et al, 2017 & Percac-Lima et al, 2014). The purpose of this practice inquiry project was to assess the use of a patient navigation (PN) strategy in improving completion rates of colorectal cancer screening.

Background

As of 2015, for every 100,000 people, 38 new cases of colon and rectum cancer were reported and 14 of those individuals died (U.S. Cancer Statistics Working Group, 2018). Colorectal polyps can be found during screening and removed before developing into cancer. If cancer is detected earlier through screening it is easier to treat, decreases health care costs, and CRC can be prevented (Rice et al, 2017). The USPSTF recommends that individuals at average risk begin screening at age 50 and continue until 75 years of age. Lower screening rates
contribute to increased mortality from the disease (CDC, 2012). The national goal for colon cancer screening set by the Office of Disease Prevention and Health Promotion’s initiative, HealthyPeople2020, is 70.5% (2019). The CDC has also set a goal of 80% completion set by the National Colorectal Cancer Round Table group (CDC, 2016). Studies have shown that increases in screening rates can result in decreases in CRC incidence and mortality (Zauber et al, 2015), yet many eligible people do not complete screening (Sabatino et al, 2012). The most recent data suggest 63.1% of females and 61.8% of males were screened in 2015 on the National Health Interview Study (CDC, 2015). Kentucky’s incidence of CRC is 48 per 100,000 individuals, the highest rate in the US (U.S. Cancer Statistics Working Group, 2018). In 2016, only 69.7% of the age-eligible population in Kentucky were screened, which is lower than both the HealthyPeople2020 target of 70.5% and National Colorectal Cancer Round Table goal of 80% (CDC, 2016).

Individuals who are considered at average risk for CRC are adults’ age 50-75 years old with absence of increased risk factors. The USPSTF considers increased risk factors to be individuals with a personal history of colorectal cancer or adenomatous polyps, a personal history of irritable bowel syndrome, a strong family history of colorectal cancer or polyps, or a known family history of a hereditary colorectal cancer syndrome such as adenomatous polyposis (FAP) or Lynch Syndrome (American Cancer Society, 2017). Despite these national guidelines, the CDC reports that of adults aged 50 to 75 years old, one in three are not being tested for colorectal cancer as recommended (CDC, 2017 and Ely et al, 2016).

Multiple barriers exist to screening completion such as insurance issues, lack of public and health care provider awareness of screening, patient beliefs, and cost (Ely et al, 2016). Other factors such as lack of access to care, health disparities, structural barriers, client’s perceptions of testing, rigor of bowel preparation for colonoscopies, and fear of testing/results can also be
contributing factors to poor screening rates (Ely et al, 2016). Evidence shows that CRC screening rates in primary care can be improved using patient reminders, provider reminders, provider assessment and feedback, reducing structural barriers, small media, professional development training, having IT support, and patient navigation (Degroff et al, 2018). The CDC promotes national initiatives to increase CRC screening rates, specifically a navigation model called the New Hampshire Colorectal Cancer Screening Program (NHCRCSP). This program effectively increased the completion rates of screening from 69.3% to 96.2% and the quality of CRC screening by addressing some common barriers (Rice et al, 2017). A navigation model can be helpful in overcoming the barriers to screening to ensure not only identification of those at risks but ensuring their completion of screening.

**Screening Methods**

Suggested CRC screening methods include stool-based tests (gFOBT, FIT, FIT-DNA), direct visualization tests (Colonoscopy, CT colonography, flexible sigmoidoscopy, flexible sigmoidoscopy with FIT) or serology tests (SEPT9 DNA) (USPSTF, 2013) (see Figure 1.) Colonoscopy is considered the gold standard or “preferred” method by the American College of Gastroenterology (ACG) for screening (2008). Colonoscopy is the preferred method because of the ability to view the entire colon and remove polyps or biopsy precancerous lesions during the test (ACS, 2019). Despite this recommendation, both the American Cancer Society (ACS) (2019) and the ACG support the use of both the cancer prevention test (Colonoscopy) and cancer detection test (fecal DNA), depending on which screening method will be accepted by the patient. Many individuals find it difficult to complete Colonoscopy due to rigor of bowel prep, transportation issues, costs, and time (ACS, 2019). The ACS and ACG state the most important method is to complete any screening at all (ACG, 2008 & ACS, 2019).
### Table 2. Characteristics of Colorectal Cancer Screening Strategies*

<table>
<thead>
<tr>
<th>Screening method</th>
<th>Frequency†</th>
<th>Evidence of efficacy</th>
<th>Other considerations</th>
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<tr>
<td><strong>Stool-based tests</strong></td>
<td></td>
<td></td>
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<tr>
<td>gFOBT</td>
<td>Every year</td>
<td>RCTs with mortality end points: High-sensitivity versions (e.g., Hemocult SENA) have superior test performance characteristics than older tests (e.g., Hemocult II)</td>
<td>Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT‡</td>
<td>Every year</td>
<td>Test characteristic studies: Improved accuracy compared with gFOBT Can be done with a single specimen</td>
<td>Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT-DNA</td>
<td>Every 1 or 3 years§</td>
<td>Test characteristic studies: Specificity is lower than for FIT, resulting in more false-positive results, more diagnostic colonoscopies, and more associated adverse events per screening test Improved sensitivity compared with FIT per single screening test</td>
<td>There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy; may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test</td>
</tr>
<tr>
<td><strong>Direct visualization tests</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colonoscopy†</td>
<td>Every 10 years</td>
<td>Prospective cohort study with mortality end point</td>
<td>Requires less frequent screening Screening and diagnostic follow-up of positive findings can be performed during the same examination</td>
</tr>
<tr>
<td>CT colonography‡</td>
<td>Every 5 years</td>
<td>Test characteristic studies</td>
<td>There is insufficient evidence about the potential harms of associated extracolonic findings, which are common</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy</td>
<td>Every 5 years</td>
<td>RCTs with mortality end points: Modeling suggests it provides less benefit than when combined with FIT or compared with other strategies</td>
<td>Test availability has declined in the United States</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy with FIT§</td>
<td>Flexible sigmoidoscopy every 10 years plus FIT every year</td>
<td>RCT with mortality end point (subgroup analysis)</td>
<td>Test availability has declined in the United States Potentially attractive option for patients who want endoscopic screening but want to limit exposure to colonoscopy</td>
</tr>
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*CISNET = Cancer Intervention and Surveillance Modeling Network; CT = computed tomography; FIT = fecal immunochemical test; FIT-DNA = multi-targeted stool DNA test; gFOBT = guaiac-based fecal occult blood test; RCT = randomized clinical trial.†—Although a serology test to detect methylated SEF19 DNA was included in the systematic evidence review, this screening method currently has limited evidence evaluating its use (a single published test characteristic study met inclusion criteria, which found it had a sensitivity to detect colorectal cancer of < 50%). § It is therefore not included in this table.‡—Appplies to persons with negative findings (including hyperplastic polyps) and is not intended for persons in surveillance programs. Evidence of efficacy is not informative of screening frequency, with the exception of gFOBT and flexible sigmoidoscopy alone.§—Strategy yields comparable life-years gained (i.e., the life-years gained with the colonoscopy strategy) and an efficient balance of benefits and harms in CISNET modeling.§—Strategy yields comparable life-years gained (i.e., the life-years gained with the colonoscopy strategy) and an efficient balance of benefits and harms in CISNET modeling when lifetime number of colonoscopies is used as the proxy measure for the burden of screening, but not if lifetime number of cathartic bowel preparations is used as the proxy measure.§—Suggested by manufacturer. Information from references 1 and 2.

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**Figure 1.** Characteristics of Colorectal Cancer Screening Tests (from American Family Physician, 2017).
Research shows that people are not always offered a choice of CRC tests, but that people who are able to choose the test they prefer, they are more likely to get the test done (CDC Newsroom, 2013). A randomized control trial of competing strategies demonstrated that when patients were given a choice of screening options between FOBT and Colonoscopy, compliance with screening almost doubled from 38% to 69%, in Colonoscopy alone (Inadomi et al, 2012).

**Cologuard**

Individuals find advantages to the fecal detection test where there is no bowel prep needed, sampling can be done at home, and there are low costs of testing (ACS, 2019). For patients at average risk, *Cologuard*, a Mt-sDNA or FIT DNA test (stool DNA) is a noninvasive, FDA approved, highly-sensitive CRC screening strategy (Exact Sciences Corporation, 2018). This screening method is a mail-in stool sample that detects altered DNA and hemoglobin in the stool, which can analyze and detect 11 distinct biomarkers that identify cancer and precancer. The screening test has high sensitivity (92% in detecting CRC stage I-IV) and specificity (87%), and is built for high compliance (68%) (Imperial et al, 2014 & Inadomi et al, 2012). A recent study found that fecal DNA testing using Cologuard was more sensitive, 92.3% in detecting colorectal cancer over fecal occult blood testing (FOBT), 73.8% (Imperiale et al, 2014). (See Appendices. 1)

These tests can be administered to individuals at average risk for CRC screening but are not indicated for surveillance in high risk individuals (Exact Sciences Corporation, 2018). A positive Cologuard results in the need for a diagnostic colonoscopy. This type of screening method has been designed to help address some of the patient preference issues such as lack of screening support (Exact Sciences Corporation, 2018). It is supported by the USPSTF and
American Cancer Society for routine CRC screening at intervals of every three years for negative results (Exact Sciences Corporation, 2019). The use of Cologuard has shown an increase in screening rates because it is less invasive, no bowel prep is needed and there is a shorter turnaround time from ordering to completion than Colonoscopy (Prince et al, 2016). Prince et al reported that there was an 88.3% intent-to-screen compliance for previously non-compliant Medicare patients when using Cologuard (Prince et al, 2016).

**Literature Review**

A patient navigator is someone who provides personal guidance to patients as they move through a health care system (American Medical Association, 2015). Currently, the role is not regulated, and a patient navigator (PN) can be a nurse, volunteer, or someone with a professional medical, legal, financial, or administrative experience background. The PN helps the patient or family member with different needs involving healthcare issues such as treatment or care options, communication with the provider, managing medical paperwork, insurance, and even accompany the patient to appointments (Simon, S. American Cancer Society, 2018). In general, a PN offers services to the patient and guidance for them through the healthcare system where needed. In particular, the method which combines patient education, patient communication, and client reminders, has been shown to improve cancer screening rates in vulnerable populations (Louden, 2015).

A systematic review demonstrated that the use of a patient navigator can increase the number of patients who complete colonoscopy or other methods of screening in the primary care setting. Typically, the methods utilized a process of guiding a patient through the screening process and providing frequent client reminders (Domingo et al, 2017). In a recent
comprehensive patient navigator program supported by the CDC called the New Hampshire Colorectal Cancer Screening Program (NHCRSP), patients were 11.2 times more likely to complete their CRC screening than those who were non-navigated (Rice et al, 2017). PN models have also been shown to increase CRC screening rates and reduce cancer screening disparities in vulnerable patients such as low-income and racial/ethnic minority groups (Percac-Lima et al, 2014 & Rice et al, 2017). PN services that assess barriers and tailor navigation services to them can have positive effects on quality of care and patient satisfaction (Post et al, 2014 & Lamanna et al, 2016). One study in an urban, university-based family medicine clinic that used a “lay cancer screening navigator” and training program for the navigator demonstrated a viable strategy that can be used in that it did increase colon cancer screening rates. It attributed most of the increase in CRC screening completion to not only the use of a navigator, but in also offering an alternative method, FIT testing in this case, as a contributing factor to increased rates since it decreased patient barriers (Liu et al, 2014).

Navigation models that provided education regarding the colon cancer process and procedures of screening through telephone or written communication have been shown to motivate and support the patient to complete screening (Domingo et al, 2017 & Kanaabi et al, 2016). Those that have been most successful are navigation services tailored to the specific screening tests, but challenges to implementing navigation services include lack of updated electronic medical record system or funding (Sabatino et al, 2012 & Domingo et al, 2017 & Post et al, 2014). Gaps identified in the review of the evidence showed lack of knowledge looking at PN interventions in individuals with private insurance (Kanaabi et al, 2016) since they have typically been most effective in vulnerable populations (Percac-Lima et al, 2014 & Rice et al, 2017 & Domingo et al, 2017). Overall, there have been viable results supporting PN to increase
uptake of CRC screening completion, although more data is needed to support their use with individuals other than vulnerable populations.

Quality Improvement Initiative

Quality improvement is a systematic, formal approach to the analysis of clinical practice and efforts to improve performance (American Association of Family Practice, 2019). It is based on determining potential areas for improvement, collecting and analyzing data, communicating results, and ongoing evaluation (AAFP, 2019). The American Association Family Practice (AAFP) notes that QI practices can help improve patient outcomes and support practices in transition to quality-based payment methods of reimbursement. Quality based payment methods include the Quality Payment Program (QPP) and the Medicare Incentive Payment Systems (MIPS) for Medicare reimbursement (AAFP, 2019). QI initiatives can prove pivotal for clinics to perform to help meet these set goals for reimbursement such as colon cancer screening. Quality improvement processes aim to collect data to understand how well the system is working and to identify potential areas for improvement (AAFP, 2019). It is an ongoing process and evaluation where decisions for changes in the process are made based on real time analysis (AAFP, 2019).

Health Belief Model (HBM)

Incorporating principles of the Health Belief Model into the quality improvement strategy and patient navigation aims to facilitate better outcomes. The HBM provides a framework for understanding health seeking behavior of individuals. It is a socio psychological model that can help us explain health seeking behaviors by looking at one’s motivational factors for and understanding of specific health actions (Sohler et al, 2015). The HBM assesses how one’s perceived susceptibility, perceived severity, perceived benefit, perceived barriers, and cues to
actions affect health behaviors and decisions (Sohler et al, 2015). Since patients’ beliefs around screening (Ely et al, 2016) have been identified as one of the largest barriers to non-completion of screening, it can be beneficial to guide interventions for colon cancer screening based on the theoretical framework of the HBM. PN can specifically target an individual’s perceived beliefs concerning screening using one-on-one interaction, communication, and patient reminders to facilitate increased uptake of screening tests. Patients frequently perceive barriers to screening such as fear of results, fear of testing, cost, transportation issues, lack of access to care, or opinions that screening is not needed (Ely et al, 2016). The principles of the HBM can help guide interactions between the patient and the navigator to meet the needs of the patient and overcome individualized barriers for non-completion of testing.

Contributing factors as mentioned in the HBM such as self-efficacy, barriers, cues-to-action, knowledge, and stage of readiness can determine achieved CRC screening completion (Sung et al, 2008). The PN takes these factors and communication techniques into consideration and uses them during the patient encounters. The HBM helps guide the PN’s interactions with each patient when discussing options of screening methods as well. In this QI project, the navigator was able to guide decision making for screening test choice based on the patient’s perceived ability to complete the chosen testing option. PN as an intervention guided by the HBM model can ensure a better chance of health behavior change surrounding CRC screening in individuals.

**Purpose**

The goal of this quality improvement project was to assess the effectiveness of a patient navigation strategy on CRC screening and completion in adults identified to be at average-risk in
a primary care women’s health clinic in an urban academic medical center. The specific aims of the project are as follows

**Aim 1:** Compare colorectal cancer screening completion rates between navigated and non-navigated patients

**Aim 2:** Identify barriers to non-completion of screening in those individuals who received navigation

**Aim 3:** Examine demographic factors among navigated and non-navigated patients including race, ethnicity, and type of insurance

### Methods

#### Study Permission

The QI project study received approval under the UK IRB, entitled *Evaluation of an Interprofessional Primary Care Training and Enhancement Program Survey Cover Letter* (Approved- 1/9/2018 IRB # 42943 ID # 10456). The intention of the QI project is to replicate and adapt the PN model strategy offered by the CDC, the NHCRCSP protocol, to a women’s health primary care clinic by examining current practice and adjusting the navigation strategy to fit this setting.

#### Setting

This QI project was completed in a women’s health primary care clinic in an urban academic medical center. The clinic consists of five physician providers and two nurse practitioners were primary care services are provided. The project was conducted from September 2018 until February 2019.
Study Population

Inclusion criteria included: 1. established female patients of the clinic age 50-75 years old
2. Patients were considered low risk and are eligible for colorectal cancer screening. Exclusion criteria are those non-English speaking, less than 50 years old, older than 75 years old, or with increased risk factors (personal history of colon cancer or colon polyp, previously positive screening test, history of inflammatory bowel disease (IBS) or other inherited syndromes; or a first degree relative with CRC.

Study Design

The study was a quasi-experimental comparison group design to assess the effectiveness of the navigation strategy on the rate of CRC screening completion and quality. Changes in colon cancer screening rates between patients who receive navigator services and those who received routine care were evaluated during the 6-month intervention period. Those patients who did not complete screening were contacted to identify barriers to completion of CRC screening during phone communication at the completion of the project.

Research Procedures & Data Collection

The QI project reviewed charts through the electronic medical record (EMR). The Clinical Quality Safety (CQS) Review system that is incorporated into the EMR identifies patients who are not up-to-date with preventative services for providers. Purposeful sampling of every other chart was reviewed for inclusion criteria from this list. Further review of the chart was done to determine if testing was performed and not documented. Charts were reviewed until 30 patients met the inclusion criteria. The sample population was then contacted on behalf of the clinic to discuss the need for colorectal cancer screening. An additional 30 patients from the CQS
system list were identified as a control group receiving routine care using the same chart review process.

In the clinic, preventative screening services for colorectal cancer are offered as colonoscopy and Cologuard, during a patient’s annual exam or established patient visit by the provider. Routine care consists of the screening test order being placed in the EMR for colonoscopy and then the patient being contacted by phone at later date by endoscopy for scheduling of testing. Endoscopy then mails a packet of instructions for the testing. If Cologuard is ordered by the provider, the ordering form is filled out that day by the patient or by the patient with help from the provider. The form is then mailed by the patient or mailed/faxed by the clinic office. The Cologuard representative will then contact the patient by telephone to set up services.

The PN services were completed by the primary investigator through telephone or clinic encounters guided by a modified protocol version of the CDC’s NHCRCSP strategy (Rice et al, 2017). The steps of the protocol used included: 1. Identify low risk patients through CQS data 2. Contact the patient to determine if they are interested in colon cancer screening because they have not completed the screening in the recommended time frame (colonoscopy or Cologuard stool DNA testing) 3. If the patient is willing to move forward with screening, schedule the appropriate test and confirm test has been scheduled, if patient prefers stool DNA testing, assist with completion of forms and follow patient updates on Cologuard provider portal (see Appendix 4.) 4. Follow up phone call prior to colonoscopy to confirm appointment and receiving bowel prep week of testing 5. If patient chooses stool DNA testing, call to confirm receipt of test kit or contact from Cologuard representative. 6. If results are not in chart or on provider portal, call patient to assess barriers to completion
The Cologuard online provider portal (see Appendix 4.) was accessed using an office login account in which results from all providers in the enterprise can be viewed. The site organizes results by patient name, provider, and clinic location. The patient’s results can be searched by name/MRN or listed by provider. The status of each patient’s order is marked as result available, kit delivered to patient, no result/reorder recommended, cancelled-suspended for inactivity, cancelled-order expired, and due for re-screening. Positive Cologuard results trigger the company to contact the patient and mail positive results to the provider and patient. Lack of integration between the online portal and the clinic’s electronic medical record currently exists. Negative results are mailed to the patient and verified by clinic office staff using the portal.

After completion of the intervention, the charts of 30 patients who received routine care were chart audited for CRC screening completion. Additionally, a chart audit was performed of those patients receiving PN services for CRC screening. The charts with absences of documentation of results in the chart and/or Cologuard provider portal were considered as non-completion. Those whose chart review indicated non-completion and received PN services were contacted to assess barriers to completion at end of project time period. During the project, enrollment forms for Cologuard through an online provider ordering portal became available.

Initially, patient navigation services in the intervention group who agreed to do stool DNA testing over the telephone were then mailed a Cologuard enrollment form and instruction sheet (see Appendix 2. and Appendix 3.) as described by the PN during the phone encounter. The patients were then contacted by the PN to verify if they received the packet or if the online provider portal did not indicate the order status as being received. For patients who agreed to Cologuard, while in the office, the PN completed paperwork during clinic visit and then mailed the form.
During the project, the order form for Cologuard became available online through an online provider portal. The remainder of the patients who received navigation were then enrolled for Cologuard through this portal during phone interaction with the PN versus the mailed packet for enrollment. Patients who were set up for Cologuard by the PN after referral from provider were done through the online ordering portal during the visit. Data collected during the medical record review was stored using REDCap, a secure web-based program created to support data capture and storage for research studies, where data is securely kept on Biomedical Informatics servers in the secure data center run by the Institute for Pharmaceutical Outcomes and Policy.

**Data Analysis**

Data analysis was performed following the 6-month navigation time period. Results were analyzed using Statistical Analysis (SAS) Software as well as Statistical Package for the Social Sciences (SPSS) software. Descriptive analysis of the sample demographics was done using frequencies with percentages for nominal variables. The primary outcome was CRC screening completion rates. The proportion of those who completed a colonoscopy or Cologuard among patients who were or were not navigated (routine care) was described using frequencies with percentages. The differences between colonoscopy or Cologuard completion between patients who were or were not navigated was determined using chi-square with fisher's exact tests and prevalence odds ratio. The secondary outcome measure looked at was barriers to CRC screening. The barriers to non-completion of colonoscopy or Cologuard were described qualitatively of those who received patient navigator services but did not complete colonoscopy or Cologuard. Since the Cologuard enrollment process changed throughout the practice improvement study, those who completed Cologuard enrollment through mailed instructions and paper forms versus online forms in the navigation group were also compared using frequencies with percentages.
Results

Sample Characteristics

The charts of thirty patients were reviewed for the routine care group. All patients were female. The demographics were similar between both groups and consistent with the overall demographics of the clinic. In the routine care group, most of the patients were 50-60 years old, 56.67%, and were Caucasian, 83.3%. The majority also had HMO insurance (40%). In the patient navigation group, thirty charts were reviewed and the demographics were similar. Forty percent of the patients were 50-60 years old, 86.67% were Caucasian, and 46.67% had HMO insurance (see Table 1.)

Increased Screening Rates

Overall, there was a 26.63% increase in completed screening rates in those patients who were in the patient navigation group versus routine care. The odds ratio for navigated patients was 5 times more likely to complete screening than the non-navigated group. Ten patients in the routine care group completed colon cancer screening and two in the routine care group. No patients completed Colonoscopy in the routine care or intervention group. Only two patients had Colonoscopy scheduled during the time frame of the project and when contacted by the PN during week of testing both had rescheduled the testing date. Six patients in the PN group and 4 in the routine care had colonoscopy scheduled with verified dates of testing available in the EMR. There was a 36.63% increase in those who completed testing or had a scheduled date for colonoscopy confirmed in EMR versus the routine care group. The odds ratio including both of these scenarios was calculated for patient navigation group to be 2.7 times more likely to have completed screening or had a scheduled colonoscopy date in the EMR compared to the control
group. (see Table 2.) Of the 10 patients completing Cologuard, 8 had negative results and 2 had positive tests. The patients were contacted by the provider to verify positive results and scheduled diagnostic colonoscopy. The scheduled dates of these were past the project end time.

Of note, the time from ordering to completion of testing was looked at for Cologuard since the data was available on the online provider portal. There were 10 patients who completed Cologuard testing in the PN group, 5 patients completed testing in less than 1 month from ordering date, 4 patients completed in less than 2 months from ordering data, and 1 patient completed testing in less than 3 months from ordering. Most patients completing Cologuard testing, 50% of the patients did so within less than 1 month from the ordering date (see Figure 2).

**Cologuard Enrollment Paper Form versus Online Form**

Of the 30 patients in the intervention group, there were 9 patients who received mailed paper forms for Cologuard enrollment after agreeing to test with the PN. There were 21 patients who were enrolled in Cologuard by the PN using the online provider ordering portal. Using the mailed paper form, five patients completed Cologuard. Out of those individuals enrolled using the online provider portal, five patients completed Cologuard. Overall of the groups, 55.5% of patients completed screening from the mailed enrollment forms versus 23.8% using the online ordering portal (see Table 3.).

**Barriers to Screening**

Barriers were assessed through telephone communication of the patients with non-completion of testing or no scheduled colonoscopy date in EMR (see Table 5.). Of the 16 patients contacted by the PN, 8 of the patients were unable to be reached after 2 phone attempts.
Of the 8 patients reached by the PN, themes for non-completion of testing were time, lack of information, or that they did not receive the Cologuard test kit. Of the patients who were to complete colonoscopy, two of the patients stated there was not enough time or work commitments contributed to them being unable to complete testing. One patient rescheduled her Colonoscopy due to fear of testing and felt she had lack of information. The other patient who rescheduled Colonoscopy stated it was due to time and being unable to take off work.

“I have been unable to take off work because my mom has been sick and I had to take off work to care for her, so I rescheduled my colonoscopy”

“I got really nervous about colonoscopy testing and rescheduled, I didn’t feel I had enough information, and was unable to find transportation, I just got scared, but I will go to the rescheduled date”

Twelve of the patients were scheduled for Cologuard and did not complete testing. The Cologuard representative was contacted for clarification and data collected for the 12 patients who status was “order cancelled for inactivity” on the provider online ordering portal at the end of the project time. Order cancelled for inactivity means the patient has the kit and has had it for at least 60 days but has not submitted it. This status means the company is waiting for the patient to complete it. Three compliance phone calls and 1 letter are sent to the patient prior to reaching this order status. If they have reached this status, they are no longer contacted by the Cologuard representatives, although their order would still be active for 365 days from the order date (Brooke Sorgi, Exact Sciences Corporation Cologuard National Account Manager, 2019).

These 12 patients were then contacted by the PN to assess barriers. 6 of these patients were unable to be reached by the PN. Of those patients able to be reached, 2 confirmed with the
PN they had not had time to complete testing kit although received it, 2 said they never received the kit, 1 was unable to give a reason for non-completion, and 1 attributed it to being unable to provide an adequate stool sample.

“I have had very liquid stool lately, but when I can give a good sample, I will contact Cologuard and send it”

**Discussion**

The findings of the QI project highlight the benefit of a PN strategy for increasing colon cancer screening in this population. Using an adapted PN protocol from the New Hampshire Colorectal Cancer Screening Program (NHCRCSP), patients were 5 times more likely to complete colon cancer screening. They were also 2.7 times more likely to at least have had their colonoscopy date scheduled. In addition, it demonstrated that among patients completing Cologuard, they were more likely to complete screening if they were mailed reminders with instructions for enrollment than by using an online ordering portal alone. Although outcomes in this QI were less than those found in the NHCRSCP study (odds ratio of 11.2 versus 5) they similar trends.

The NHCRCSP is a patient navigation model for public health that was highly effective at increasing screening completion and quality of colonoscopy for low income, underinsured groups. The navigated patients were 11.2 times more likely to complete their colonoscopy than non-navigated patients (Rice et al, 2017). The CDC has a protocol manual to help others replicate the model. The protocol used in this QI project was modeled after the NHCRCSP but modified to fit the different clinical setting. This QI initiative showed that navigated patients
were 5 times more likely to complete colon cancer screening than the non-navigated patients in comparison to 11.2 times in the NHCRSCP model.

Some of the main differences in this model were the setting and demographics of the groups receiving patient navigation. Their protocol looked at 131 patients receiving navigation versus 75 who were non-navigated. They evaluated average and increased risk groups while this QI project only looked at low risk individuals. Another difference was that their model goal was to complete only colonoscopies over a 12-month timeframe while this QI project offered both Colonoscopy and Cologuard as options for screening in a 6-month timeframe.

The NHCRSCP consisted of 6-steps; “topics” were described in detail to guide the interactions between the patient and patient navigators with extensive partnerships in the care system. They had strong collaborations with the endoscopy center and more than one patient navigator in which the QI project in this setting lacked both (Rice et al, 2017). The NHCRSCP suggested that a limitation of the study was that it did not offer alternative screening methods such as fecal occult blood test or fecal immunochemical tests and adaptation of this program including alternative testing options in the future would be useful. The results of this QI showed that individuals offered an alternative screening test (Cologuard) during PN were more likely to choose this option in that 10 navigated patients completed Cologuard and 0 had completed colonoscopies at the end of the project.

There are several factors that may have contributed to the effectiveness of this model. One was having a single patient navigator. The navigated patients received phone calls from a single navigator who actively tried to establish a relationship with the patient. The navigator was also an RN who was an expert in the online ordering portal offered by Cologuard. The short time
frame of the study also contributed to the frequency and timing of calls delivered. Having one consistent navigator and screening enrollment process could have influenced the patient’s willingness to complete screening. Another factor was that the patient navigator was able to offer two forms of screening tests. During phone encounters with the patients many declined Colonoscopy but were willing to complete Cologuard. Giving patients an option seemed to increase their likelihood to completing the test. In this setting, the providers were also able to order testing for Colonoscopy in the electronic medical record (EMR) but had no ability to order Cologuard or verify results in the EMR. This factor may have contributed to the effectiveness of the processes used for Cologuard enrollment by the PN versus if the clinic did have Cologuard ordering embedded in the EMR. Since the overall results in this QI were consistent with those of the NHCRSCCP although not as strong, the ability to replicate more aspects of this model could increase the effect of a PN strategy in this setting.

Given the significant finding of the use of mailed enrollment instructions for Cologuard, in which 55.5% of patients completed testing versus 23.8% in those enrolled on the online portal, a recommendation for the future could include both mailed reminders for screening enrollment processes and order placement in the online portal. Patient navigation in this study also showed that having one designated personnel to organize enrollment could have contributed to increased screening completion. If one person is not designated, then having a standardized enrollment system for all providers can also be key. An important area for future research could include using a standardized screening enrollment process or a proposed mailed screening form (see Appendix 5) for patients requiring screening. An algorithm of the protocol that can be used for patient navigation services in the future was also developed (see Appendix 6).
Limitations

Limitations of the project were small sample size and lack of demographic variation. The majority of the patients were Caucasian (86.67% in intervention group and 83.3% in control group) with HMO insurance (46.6% in intervention group and 23.3% in control group). This prevents results from this study to be generalized to other settings such as the success of the NHCRSCP in vulnerable populations. Another limitation was the long time period of scheduling colonoscopy. Time to scheduling of colonoscopy from ordering the test was longer than the time frame of the study, 6-months. For this reason, no colonoscopy results were available, although scheduling dates were assigned. Patients who scheduled their colonoscopy still did not complete it. Since the scheduling dates were past the time period of the project, the use of patient navigation for completing colonoscopy as the chosen screening method was unable to be analyzed. In addition, lack of consistency in provider documentation and variations of charting for CRC screening test completion made it difficult to determine who needed screening in the control group. Also, results from outside facilities were not available and therefore could have hindered results of those considered non-completion in this group.

Future Recommendations

Clinical Practice

The findings of this QI confirm the importance of developing CRC screening improvement interventions in the future since rates of completion did improve. Improvements in screening processes are necessary for healthcare facilities moving to quality-based payment for insurance reimbursement. It is now more important than ever since new guidelines by the American Cancer Society (ACS) are recommending average risk screening begin at age 45
contrary to the current age of 50. The ACS’s data shows that new cases of colorectal cancer are occurring at increasing rates among younger adults (ACS, 2018). This change in recommendation will increase the population requiring screening. Within these guidelines multi-target stool DNA testing every 3 years is an acceptable form of screening by the ACS. Since the number of individuals requiring screening will increase significantly, alternative forms of screening, non-invasive methods, and timely screening methods such as stool DNA testing can truly make an impact on increasing the number of individuals who are screened. Evidence from this QI project supports this in that there was 36.6% increase in screening completion and all the patients completing testing performed Cologuard.

This practice improvement project suggests that giving patients the choice, reducing time from ordering to scheduling, clinics providing patient support for testing enrollment form completion, and using an organized system connected to the EMR can help increase screening rates. These findings are consistent with the American Cancer Society’s emphasis that individual preference, choice in testing options, and strong follow-up are needed to have positive results (2018). Patient navigation is a method that can help combine these factors in the future. Patient navigation is a strategy that may prove useful in the future for reaching individuals requiring screening.

Summary

Colorectal Cancer in the United States is among the most widespread cancers with significant disease burden if not diagnosed early. Prevention and early recognition of the disease are key to making an impact on reducing mortality and morbidity from the disease. Primary care providers are vital in recommending screening to patients for prevention, although they are not
the only factor that can help increase disease screening rates. The importance of increasing screening rates now more than ever is due to changes in the ACS guidelines proposing screening now be done at a younger adult age of 45 instead of 50 (ACS, 2019). Thus, the population at risk will increase drastically.

Suggestions for improving CRC screening rates are giving patients at average risk a choice between screening methods, utilization of an online ordering portal, mailed screening enrollment reminders, reducing time between ordering and scheduling of screening tests, and a platform for ordering alternative screening methods to Colonoscopy that are embedded into EMR’s. Having a systematic approach that involves the electronic medical record across the entire healthcare system such as patient navigation can help improve rates. Using quality improvement methods can make a difference in clinical practice for standardizing CRC screening processes for increasing screening rates.
Appendix 1.

_Cologuard at Home Testing Instructions, Mailed to Patient with Kit by Exact Sciences Corporation_
Appendix 2.

*Mailed Screening Enrollment Instructions*

To:

From: Women’s Health Clinic

Date:

You have expressed interest in doing the Cologuard test to complete your colon cancer screening. Please fill out the form attached that has been filled out by your healthcare provider. If you have any questions please call ***.***.***

1. Contact your insurance company to determine insurance coverage, information is provided.
2. Complete your form
3. Submit your form through one of the options below
   a. Bring form to Women’s Health Clinic
   b. Fax to 844-870-8875
   c. Mail form to EXACT SCIENCES LABORATORIES 145 E. Badger Rd, Ste 100, Madison, WI 53719
EFFECT OF A PATIENT NAVIGATOR OF CRC SCREENING

Appendix 3.

Cologuard Order Requisition Paper Form

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**Patient Demographics**

Attach a copy of the front & back of primary and/or secondary insurance cards.

**Patient Insurance/Billing Information**

Only completion of "Policyholder Name" and "Policyholder DOB" is necessary when attaching a copy of the front & back of primary and/or secondary insurance cards.

---

Fax completed form to 844-870-8875
Appendix 4.

Exact Sciences Cologuard Online Provider Portal Screenshot
Appendix 5.

*Suggested Screening Enrollment Instructions Form for Mailing*

To:

From: Women's Health Clinic

Date:

You have received this letter because you are eligible to receive screening for colon cancer. Our records indicate you are due for screening or repeat testing. Please call the office at ***-***-*** to make an appointment to discuss screening options and your risk of colorectal cancer with your healthcare provider. If you have already done so, this is a reminder to proceed with the options below.

1. If it is determined, you are due for Colonoscopy and the order has been placed please contact Endoscopy scheduling at ***-***-***
2. If it is determined, you are due for Cologuard (fecal stool DNA testing) please submit your enrollment form through one of these options below
   a. Bring form to UK Women's Health Clinic or call office so we can place order online
   b. Fax to 844-870-8875
   c. Mail form to EXACT SCIENCES LABORATORIES 145 E. Badger Rd, Ste 100, Madison, WI 53719

If you would like to discuss any of these options further or decide what test is right for you based on your risk, please contact the office. If you have recently completed colon cancer screening, please disregard this letter.
Appendix 6.

*Patient Navigation Proposed Protocol*
Colon Cancer Screening Protocol Algorithm with/without Patient Navigator

Scenario 1 (PN)
- If patient is under PN services then mailing form will be submitted if no screening results are in EMR after follow up phone call

Scenario 2 (chart audit)
- Form can be mailed to those patients identified as not up to date on CQS list by patient support (CST, clinic nurse, or PN)

Scenario 3 (provider driven)
- If provider indicates screening is needed during visit, referral to CST to mail form or give form to patient during visit

If patient contacts clinic regarding arrangement of screening, task is placed to provider to order colonoscopy in EMR, order is placed in Cologuard online ordering portal, or chart is updated to screening status current

If colonoscopy order in placed in EMR, patient is contacted by endoscopy

If Cologuard form is submitted through mail or online portal, patient is contacted by Cologuard staff

Cologuard test results verified on online portal by PN, clinic nurse, or CST and task sent to provider for results
Table 1.

**Sample Characteristics**

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Navigation Group N=30</th>
<th>Percentage of group</th>
<th>Non-navigation Group N=30</th>
<th>Percentage of group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-60 years</td>
<td>13</td>
<td>43.3%</td>
<td>17</td>
<td>56.67%</td>
</tr>
<tr>
<td>60-70 years</td>
<td>12</td>
<td>40%</td>
<td>10</td>
<td>33.3%</td>
</tr>
<tr>
<td>70-75 years</td>
<td>5</td>
<td>5%</td>
<td>3</td>
<td>10%</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>26</td>
<td>86.6%</td>
<td>25</td>
<td>83.3%</td>
</tr>
<tr>
<td>African American</td>
<td>2</td>
<td>6.67%</td>
<td>3</td>
<td>10%</td>
</tr>
<tr>
<td>Asian</td>
<td>2</td>
<td>6.67%</td>
<td>2</td>
<td>6.67%</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>5</td>
<td>16.67%</td>
<td>9</td>
<td>30%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>7</td>
<td>23.3%</td>
<td>2</td>
<td>6.67%</td>
</tr>
<tr>
<td>HMO</td>
<td>14</td>
<td>46.67%</td>
<td>12</td>
<td>40%</td>
</tr>
<tr>
<td>PPO</td>
<td>4</td>
<td>13.3%</td>
<td>7</td>
<td>23.3%</td>
</tr>
</tbody>
</table>
Table 2.

**Outcome Measures**

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Navigation Group N=30</th>
<th>Non-Navigation Group N=30</th>
<th>Odds Ratio</th>
<th>P-value (chi-square)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening Completion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cologuard</td>
<td>10</td>
<td>2</td>
<td>6.67%</td>
<td></td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>2</td>
<td>6.67%</td>
<td>5 (P=.021)</td>
</tr>
<tr>
<td>Screening completion + Colonoscopy date scheduled in EMR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cologuard completion</td>
<td>10</td>
<td>2</td>
<td>6.67%</td>
<td></td>
</tr>
<tr>
<td>Colonoscopy completion</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colonoscopy scheduled date in EMR</td>
<td>6</td>
<td>4</td>
<td>13.3%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>6</td>
<td>16.67%</td>
<td>2.7 (P=.015)</td>
</tr>
</tbody>
</table>

Table 3.

**Difference in Mailed versus Online Cologuard Enrollment Table**

<table>
<thead>
<tr>
<th>Mailed Screening Enrollment Instructions (N=9)</th>
<th>Completion of Screening No. (%)</th>
<th>Non-completion of Screening No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5 (55.5)</td>
<td>4 (44.4%)</td>
</tr>
</tbody>
</table>
Table:
| Enrollment Form in Online Ordering Portal (N=21) | 5 (23.8) | 16 (76.2) |

**Figure 2.**

**Time to Cologuard Completion Graph**

![Time to Cologuard Completion Graph](image-url)
Table 4.

Expressed Barriers to Non-completion of Colon Cancer Screening Among Navigated Patients

<table>
<thead>
<tr>
<th>Barriers to Non-completion</th>
<th>Lack of transportation</th>
<th>Lack of time/out of town</th>
<th>Fear of testing</th>
<th>Did not receive kit</th>
<th>Unable to provide adequate stool sample</th>
<th>Lack of information around testing</th>
<th>Unable to reach patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-completions Cologuard</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Non-completions Colonoscopy</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

***Total N=16, number of times theme was identified upon barrier assessment***
Figure 2.

*Time to Cologuard Completion Graph*
Time to Cologuard Completion

- <3 months: 1
- <2 months: 4
- <1 month: 5

References


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Counseling. 98(7), 901-907.


