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The Effect of a Provider-Based Educational Program on Knowledge, Attitudes, Self-Efficacy, and Order Rates of Cologuard® in a Primary Care Clinic

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Dr. Sharon Lock, Advisor

DNP Final Project Report

The Effect of a Provider-Based Educational Program on Knowledge, Attitudes, Self-Efficacy, and Order Rates of Cologuard® in a Primary Care Clinic

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Abstract

BACKGROUND: Colorectal cancer is one of the most common and deadly cancers, particularly in persons greater than 50 years of age. Most colorectal malignancies are slow-growing, making regular screening increasingly important to decrease morbidity, mortality, and cost of treatment. Cologuard® serves as an effective and non-invasive colorectal cancer screening modality for average-risk adults.

PURPOSE: The purpose of this study was to evaluate the impact of a provider-based educational intervention on the knowledge, attitudes, self-efficacy, and ordering rates of Cologuard® among primary care providers.

METHODS: This study was a single-center, pre/post implementation study of the effectiveness of a provider-based educational intervention using a validated resource tool from the American Cancer Society. The first stage of the project featured a pre/post-test examination of the knowledge, attitudes, and self-efficacy related to Cologuard® of 14 primary care providers before and after an educational intervention for providers in November 2018. The second stage of the project included a separate pre/post-test design to determine the effect of the educational intervention on provider order rates of Cologuard® using 200 randomly selected charts prior to the intervention during the months of August through October 2018, and 200 randomly selected charts after the intervention during the months of December 2018 through February 2019 for patients meeting screening qualifications.

RESULTS: Of the 18 providers who attended the educational program, 14 completed and returned pre- and post- tests. There was a statistically significant increase in provider knowledge ($p<0.001$) and self-efficacy ($p=0.002$) from the pre- to post- intervention periods. There was no

statistically significant difference in attitudes (p=0.142) or Cologuard® order rates (p=0.660) from the pre- to post- intervention periods.

CONCLUSION: Provider-based educational programs serve as an effective intervention to address certain measures in practice. Increases in provider knowledge and self-efficacy related to Cologuard® were seen in the post-intervention period, and while there was not a statistically significant difference in provider attitudes, it is important to note an increase on the measurement scale did occur. Future implications for practice may involve alternate solutions to improving Cologuard® order rates, though this initiative may provide necessary first-steps to facilitate organizational changes that would lead to an increase in Cologuard® orders.

The Effect of a Provider-Based Educational Program on Knowledge, Attitudes, Self-Efficacy, and Order Rates of Cologuard® in a Primary Care Clinic

Introduction

In the United States, colorectal cancer (CRC) is the third most prevalent cancer and second deadliest cancer, with 139,992 new cases diagnosed and 51,651 deaths occurring in 2014 (Centers for Disease Control and Prevention [CDC], 2017b). Most colorectal malignancies are slow-growing, making regular screening important in decreasing morbidity and mortality. According to the American Cancer Society (ACS), preventive screening and early detection of pre-cancerous or cancerous growths greatly improve survival rates and decrease costs associated with long-term treatment (2014). The U.S. Preventive Services Task Force (USPSTF) has issued a Grade A recommendation for CRC screening to begin at age 50 for average-risk adults, continue until age 75, and incorporate methods such as fecal occult blood testing, sigmoidoscopy, or colonoscopy (2015).

Although CRC screening rates are on the rise, an opportunity exists for providers to better screen patients and discuss available screening options, thereby increasing screening uptake rates and improving overall outcomes. Providers play a pivotal role in decreasing CRC by recommending screening to eligible patients. Provider recommendations are one of the main determinants in predicting the utilization of preventive services (Atassi, 2012).

While colonoscopy remains the gold standard among CRC screening modalities, patients may have an aversion to this procedure or would prefer less invasive options. Cologuard®, the only single-test screening modality available in the U.S. to combine a multi-target stool DNA test with fecal immunochemical testing (FIT), serves as an effective method to detect adenomas and CRC for patients preferring alternative screening options (ACS, 2017a). The purpose of this

project was to determine the effectiveness of a provider-based educational intervention on the knowledge, beliefs, self-efficacy, and ordering rates of Cologuard® in a primary care clinic.

Background

In 2015, approximately 774,000 deaths worldwide resulted from CRC (World Health Organization [WHO], 2018). Of those who develop colorectal malignancies, 90% are in persons 50 years and older (ACS, 2014). In the U.S., morbidity and mortality due to CRC far exceeds most other cancers (CDC, 2017b). Kentucky's CRC incidence rates rank among the highest in the nation, with an incidence rate of 49.4 per 100,000 persons and fatality rate of 17 per 100,000 persons in 2014 (CDC, 2017a).

Screening Recommendations

CRC screening is defined by the American College of Gastroenterology (ACG) as the process by which early-stage cancers and pre-cancerous growths are detected in asymptomatic persons without previous history of malignancy or pre-cancerous cells (Rex et al., 2017). The CDC (2019) and USPSTF (2015) recommend the screening process begin at age 50 through age 75 for all persons with average-risk of developing CRC using colonoscopy, flexible sigmoidoscopy, or stool-based tests. These two organizations suggest providers use special clinical consideration for CRC screening in African Americans, but maintain age 50 as an appropriate age to begin screening (Williams, 2016). With evidence to suggest that CRC incidence and mortality is greater in African Americans, the ACG recommends screening in this patient population to begin at age 45 (Rex et al., 2017). In 2018, the ACS updated their recommendations for average-risk adults of any racial or ethnic group to begin screening at age 45 and end at age 75 or a projected life expectancy of more than ten years beyond age 75 (ACS, 2018).

When discussing CRC screening with patients, it is important for the provider to be aware of evidence-based clinical recommendations. Exceptions for 'average-risk' persons include the following:

a) Symptomatic (experiencing signs or symptoms of potential colorectal disease, including but not limited to: lower abdominal pain, bloody stools, positive guaiac or FIT test)
b) Personal history of CRC or adenomatous polyps
c) Family history of CRC (first-degree relative with CRC or advanced adenoma diagnosed <60 years of age OR two first-degree relatives with CRC or advanced adenoma)
d) Personal history of inflammatory bowel disease (such as Crohn's disease or ulcerative colitis)
e) Hereditary colorectal cancer syndrome (such as familial adenomatous polyposis [FAP] or Lynch syndrome)
f) Personal history of radiation to the abdomen or pelvis
g) Personal history of surgical CRC resection

(Centers for Medicare and Medicaid Services [CMS], 2014; Rex et al., 2017; USPSTF, 2015).

Persons at greater-risk for developing CRC should consult with their healthcare provider about screening recommendations, including age to begin screening, appropriate screening strategy, and follow-up intervals.

Screening Modalities

Joint guidelines separate CRC screening options into cancer prevention tests and cancer detection tests. Colorectal cancer prevention tests are preferred and should be offered first, due to the ability to directly visualize the colon and capture imaging of malignancies or polyps. While CRC detection tests have lower sensitivity for polyps and malignancies compared to imaging tests, these options are validated for their use in practice and should be offered to patients who decline colonoscopy or other CRC prevention tests (Rex et al., 2017). A positive (or abnormal) screening result from any CRC detection test requires a follow-up colonoscopy to further investigate. It is important to note that older guaiac-based fecal occult blood testing should not be used for screening. CRC screening recommendations of the most commonly used modalities are summarized in Table 1.

Cologuard®

Although CRC prevention tests—such as colonoscopy or flexible sigmoidoscopy—are the preferred screening modality, early detection tests are widely used and play an important role in CRC screening (Rex et al., 2017). Many patients have an aversion to invasive exams, or have issues with accessibility or availability in regards to medical procedures. Evidence from the ACS suggests a large proportion of patients, when given the choice of invasive exam versus stool-based tests, prefer the less invasive option (2017a). Additionally, modeling studies propose that outcomes of high-quality stool-based screening tests are nearly comparable to colonoscopies when strict adherence to screening intervals and appropriate follow-up occur (ACS, 2017a).

Deoxyribonucleic acid (DNA) biomarkers are shed into the stool as colorectal cancers grow and adenomas degenerate. Cologuard®, the only single-test screening modality available in the U.S. to combine FIT with a multi-target stool DNA test, serves as an effective method to

detect even trace amounts of these molecular markers for CRC and pre-cancerous neoplasias (ACS, 2017a). Because Cologuard® is a fairly new test, with Food and Drug Administration (FDA) approval just within the past five years, technology and data about this modality are still evolving. However, data across numerous organizations and studies reveals a pattern of much higher sensitivity compared to all other stool-based tests (Song & Li, 2016; ACS, 2017a).

One systematic review of several large randomized-controlled trials reveals Cologuard® as 92.3% sensitive in detecting CRC, whereas FIT testing alone averaged a sensitivity of 73.8% (Song & Li, 2016). These numbers vary only slightly when compared to figures from studies published by the ACS. Cologuard® proved to be much less specific, however, than its FIT screening counterpart. The same literature review conducted by Song and Li (2016) revealed specificity of 86.6% for Cologuard®, and specificity of 94.9% for FIT testing; these percentages are akin to those distributed by the ACS. A positive test result warrants follow-up with a colonoscopy. Repeat screening with Cologuard® is recommended every three years for patients with a negative screening result.

Cologuard® is a favorable test for patients preferring alternative screening options, as it is safe, commonly used in primary practice, and is covered by most insurers, including Medicare and Medicaid in the state of Kentucky (CMS, 2014). Unlike many other stool-based tests, results from Cologuard® are not affected by medication or food, and require only a single bowel movement to complete screening (ACS, 2017a). For patients who choose Cologuard®, the screening kit is mailed directly to the patient's home, contains directions in English and Spanish with the kit, and includes a pre-addressed, pre-paid box for shipping the sample directly to the Direct Sciences lab once a patient collects it. Patients facing lack of access to care, limited availability for bowel prep or travel, or who prefer less invasive modalities can benefit from

Cologuard®. One main takeaway for providers is any screening is better than no screening, and providing the patient with screening options does improve screening uptake rates (ACS, 2017a).

Provider Education to Impact Screening

Provider-based interventions are one strategy that can be used to influence CRC screening rates. A randomized controlled trial (RCT) by Lane, Messina, Cavanaugh, and Chen (2008) focused on provider education as an intervention to improve CRC screening and patient adherence to screening recommendations. The intervention included a PowerPoint presentation of materials, interactive questionnaires, discussion of behavioral approaches, and distribution of educational resources to providers in the experimental group. The control group did not receive the educational intervention. The results of that study revealed a statistically significant increase in patient self-reports of providers recommending CRC screening in the intervention cohort compared to the control group ($p=0.04$). Additionally, short and long term improvement in completion of CRC screening occurred among patients seen by providers in the experimental group, including a 16% increase from baseline screening rates after 1 year ($p<0.001$) (Lane, Messina, Cavanaugh, & Chen, 2008).

Another RCT in Appalachian Kentucky used academic detailing—an educational outreach method whereby trained healthcare professionals travel to practice sites to deliver evidence-based information to other healthcare workers—as the provider-based intervention (Dignan et al., 2014). At the cessation of the study, colonoscopy orders increased for intervention sites that recommended CRC screening ($p<0.01$) (Dignan et al., 2014).

One study by Sheinfeld-Gorin et al. (2000) used a pre- and post- test design to determine provider knowledge and identify potential screening barriers in an underserved urban community. The investigators of this study selected a provider-based educational session, again

using academic detailing, as the intervention. The findings included a statistically significant difference in provider knowledge scores before and after the educational intervention ($p<0.001$) over an 18-month period. Providers in the intervention group also reported significantly fewer barriers to screening practices in the post-test period than providers in the control group ($p<0.05$) (Sheinfeld-Gorin et al., 2000).

A descriptive study by Rim et al. (2009) used surveys to examine the relationship between knowledge, attitudes, beliefs, and CRC screening practices of 109 healthcare professionals, including nurses and providers. The results revealed a strong association between provider knowledge and higher CRC screening rates ($p=0.02$), but no statistically significant correlation between attitudes, beliefs, and CRC screening practices (Rim et al., 2009). Additionally, the CRC screening practices of individual providers had no statistically significant correlation to increased rates of patients screened.

Addressing Barriers to Screening

Screening for CRC has the potential to detect cancerous and pre-cancerous lesions at early stages, thereby improving long term survival rates. Despite clinical recommendations, about one-third of adults ages 50-75 have not been screened for CRC (ACS, 2017a). A recent study by the CDC revealed that underwhelming CRC screening rates may be attributed to patient evasion of tests because of bowel preparation, unfamiliarity about screening options, fear of invasiveness from colonoscopy, fear of complications, negative familial history, lack of symptoms, unawareness by the provider to screen, and absence of recommendation in general by the provider (Cooper & Gelb, 2016). Additionally, disparities among minority populations, uninsured persons, and persons of lower income levels exist when evaluating CRC screening and follow-up screening (ACS, 2017a). A literature review conducted by the ACG revealed one of

the biggest disparities exists among African American populations, as socioeconomic and genetic factors likely influence lower CRC screening rates and higher instances of morbidity and mortality (Rex et al., 2017). Men and women of all ethnicities and races can develop CRC, with slightly higher incidences in male populations; the risk of developing CRC increases after age 50 for both genders (CDC, 2017b).

Using a multiple-option approach, whereby the provider offers and discusses two or more screening tests to the patient, is a recommended strategy that the ACG suggests in order to encourage informed decision-making and increase CRC screening follow-through (Rex et al., 2017). Patients are more likely to embrace preventive health if the services are recommended by a healthcare provider (Atassi, 2012).

Theoretical Framework

In 1975, Icek Ajzen and Martin Fishbein began reviewing studies in an attempt to prove that intention, rather than attitude toward a particular behavior, was the driving cause behind the behavior. With this assumption, the Theory of Reasoned Action (TRA) was formed in 1980. Ajzen and Fishbein's TRA framework ascertained that behavior is voluntary and carried out upon intent at a certain time. Intention, by definition, is a willing and purposeful drive behind a behavior and aids in predicting whether or not a person will participate in the given behavior (Ajzen & Fishbein, 1980). The TRA model pertained only to voluntary actions (volitional control). Instances that lacked volitional or purposeful control threatened the validity of the TRA model, so the Theory of Reasoned Action was revised into the Theory of Planned Behavior (TPB), which is simply the TRA model plus the perceived behavioral control factor.

Ajzen and Fishbein determined that intention to perform a behavior is determined by the following four paradigms: (a) *attitude*, which encompasses a person's positive or negative

assessment of an action, (b) *subjective norms*, or the perceived expectation a person believes others have of a given behavior, (c) *volitional control*, which is simply the conscious decision to do or not do an action, and fourth, (d) *behavioral control*, defined as one's perception of how easy or difficult a task will be.

Attitudes

The first of these factors is attitudes, which describe the value one places on a certain behavior and affect the odds of a person to perform that behavior (Ajzen & Fishbein, 1980). For example, if a provider views CRC screening as beneficial, his or her attitude will be favorable and the likelihood of screening for CRC will be greater. Adversely, if a provider views a behavior as negative, harmful, inconvenient, or not valuable, then it is less likely for that person to suggest the given behavior.

One strategy that can be used to assess provider attitudes is a questionnaire using open-ended responses or a measurement tool, such as the Likert scale. If the questionnaire reveals positive provider attitudes, corroboration and assurance from other healthcare personnel can reinforce those beliefs. After identifying providers who do not have a positive attitude toward CRC screening, it may be helpful to reiterate the risks of CRC, as well as benefits of regular screening with support from facts obtained from the CDC, USPSTF, and other organizations. Following the premise of the TRA/TPB model, a positive change in attitude will lead to increased screening behaviors by providers, which could ultimately impact screening uptake rates by patients.

Subjective Norms

The second factor influencing intention is *subjective norms*, which answers the question, "How do I think others feel about this behavior?" This construct of the TRA/TPB model

deals with the perceived notions of others, rather than explicit expectations (Ajzen & Fishbein, 1980). The understanding an individual has about whether referent groups will approve or disapprove of an action influences the probability of that individual to participate in a given behavior. Examples of 'referent individuals' include friends, coworkers, role models, or anyone else who an individual aims to please. Healthcare providers are among the most influential of the referent groups (Atassi, 2012).

Using this construct of the TRA/TPB model, it can be inferred that a provider who believes people within the medical community place importance on CRC screening, has coworkers who utilize screening, or believes that society supports screening and surveillance, would have the intention of pleasing these groups of individuals by following screening recommendations. On the contrary, if one did not feel that referent groups believed in and standardized the practice of CRC screening, he or she would be less likely to screen patients. Offering verbal support of screening, adhering to guidelines and specific practice sites' recommendations for screening, and being a champion for CRC screening within the medical community are ways providers can act as referent individuals to other healthcare workers.

Volitional Control

Volitional control purports that one can freely and deliberately exercise the power to act upon a decision (Ajzen & Fishbein, 1980). It is the third factor of the TRA/TPB model to influence intention. Despite strong recommendations from evidence-based guidelines, the conscious decision to discuss, order, and refer screening is ultimately left up to the provider. Similarly, patients have the right to refuse medical services, thus exercising volitional control on the situation.

Behavioral Control

Not all situations and environments allow for volition, especially when more than one outside factor or determinant is present. Behavioral control, which is an assumption of ease versus difficulty of a behavior, is more useful in determining behaviors in low-volition circumstances (Gochman, 1997). This construct deals with the *perceived* control over an action, rather than the actual ability of carrying out the action.

For example, a provider with strong perceived control of screening may believe he or she has time to discuss screening, has resources readily available, or has an appropriate level of knowledge and understanding about CRC screening. Based on the TRA/TBP theory, a provider who feels that CRC screening is without major challenges will have greater intent to carry out screening. A healthcare professional with weak perceived control, however, might view CRC screening as an action that is unmanageable. This provider might feel that screening is too cumbersome or cannot be achieved during a specific time period. Assessing providers' perceptions of screening barriers is one way to determine behavioral control and subsequently formulate solutions.

Purpose

The purpose of this project was to determine if a provider-based educational intervention would increase primary care providers' (a) knowledge of current Cologuard® recommendations and procedures for use; (b) attitudes about Cologuard®; (c) self-efficacy of prescribing Cologuard®; and (d) ordering rates of Cologuard®. This project was part of a larger quality improvement (QI) initiative in a large primary care clinic.

Methods

Design

This study was a single-center, pre/post implementation study of the effectiveness of a provider-based educational intervention using a validated resource tool from the ACS. The first stage of the project featured a pre/post-test examination of the knowledge, attitudes, and self-efficacy related to Cologuard® of 14 primary care providers before and after an educational intervention for providers in November 2018. The second stage of the project included a separate pre/post-test design to determine the effect of the educational intervention on provider order rates of Cologuard® using 200 randomly selected charts prior to the intervention during the months of August through October 2018, and 200 randomly selected charts after the intervention during the months of December 2018 through February 2019 for patients meeting screening qualifications.

Setting

This project took place at a primary care clinic in central Kentucky. This institution primarily serves residents of central Kentucky seeking an array of comprehensive services, including preventive medicine, screening, wellness exams, care for chronic conditions, and acute medical visits.

Quality Improvement

Several solutions exist to address the problem of subpar CRC screening rates, including patient-based interventions and processes aimed at provider or community health center practice improvement. QI teams may provide valuable information to a clinic by conducting performance reviews, identifying weaknesses in practice, and creating/monitoring improvement processes (Agency for Healthcare Research and Quality [AHRQ], 2013).

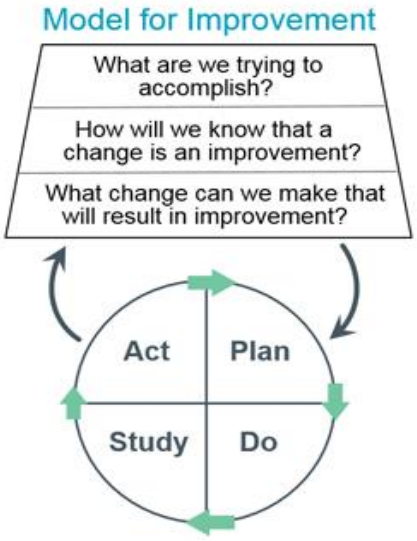
The preventative health QI team in the clinic included several interdisciplinary members from the areas of nursing, medicine, administration, and ancillary staff. The goal of the QI team was to identify a problem within the clinic (underutilization of Cologuard®) and formulate processes (Plan-Do-Study-Act cycles) to change the problem (increase acceptance and order rates of Cologuard®). Monthly team meetings were held to discuss progress and make adjustments to the improvement cycles as necessary. The timeline for meetings began in February 2018 through September 2018, with a presentation of team efforts occurring at a clinic meeting in November 2018.

Plan-Do-Study-Act Cycles

Plan-Do-Study-Act (PDSA) cycles are a common approach of QI teams to produce practice improvement that is driven by a change (AHRQ, 2013). PDSA cycles aim to answer three main questions: "What are we trying to accomplish? How will we know that a change is an improvement? What change can we make that will result in improvement?" (Institute for Healthcare Improvement [IHI], 2019). The IHI (2019) outlines four cyclical steps of the PDSA approach. The first step in the PDSA cycle is Plan, which includes strategizing how tests or observations can be used to collect data, stating an objective, predicting intended and unintended consequences, and developing a blueprint to test the change. This portion of the PDSA cycle should answer "who, what, where, when, and how." The second step is Do, which involves trialing the test on a small scale, recording outcomes and observations, and beginning to analyze data. Study is the third step, when members are tasked with completing data analysis, comparing actual outcomes to the predicted outcomes, summarizing data, and reflecting on what they learned. Finally, the Act stage involves taking what was learned from the test and making

necessary edits to the change. Figure 1 illustrates the four phases as a sequential process that can be repeated to produce multiple cycles in order to drive change.

Figure 1: *PDSA Steps*



(IHI, 2019).

For the Plan phase, the QI team identified CRC screening as the subject of process improvement, hypothesized ways to increase screening rates, and proposed an intervention aimed at addressing underutilization of Cologuard® in the clinic. The Do phase of the PDSA cycles was an in-person provider education session during the clinic's Combined Team meeting in November 2018, co-led by the primary investigator (PI) of this project and a resident from the QI team. Data analysis occurred during the Study phase. This project report does not include the Act phase.

Educational Intervention

The "*Clinician's Reference: Stool-Based Tests for Colorectal Cancer Screening*," (ACS, 2017a) was selected as a part of the provider-based educational intervention. The toolkit—which combines recommendations from the ACS, CDC, and USPSTF—was an optimal solution because it is geared toward primary care providers and summarizes the endorsements from

several health organizations in a concise, straightforward, and easily presented format. The reference tool features evidence-based facts, recommendations for practice, and comparisons among various stool tests. It focuses on empowering the provider to have a dialogue with patients who favor stool-based screening options.

The first part of the project involved a pre/post-test design to examine primary care providers' knowledge, attitudes, and self-efficacy related to Cologuard®, with the independent variable between the pre/post-survey being a provider-based education session. A co-presentation with the QI team's lead resident incorporated an overview of PDSA cycles and the clinic's current procedures for ordering Cologuard®. Currently, the clinic's procedure for providers ordering Cologuard® includes: provider and patient agree upon Cologuard® as screening modality; clinic staff (provider, nurse, or certified surgical technologist [CST]) fills out the order sheet; staff faxes order sheet directly to Direct Sciences laboratory; Cologuard® sends test kit directly to patient; patient mails sample to lab within 24 hours of collection (if no sample is received within 60 days of order date, provider is notified by fax); provider receives test results via fax approximately two weeks after sample is received. This information was reviewed using a PowerPoint presentation created by the lead resident. The Clinician's Reference was then projected onto a screen, and the PI reviewed its content aloud to those in attendance at the meeting.

Sample

Providers

Inclusion criteria for this sample included primary care providers (attending physicians, resident physicians, and advanced practice providers [APP]) who attended the clinic's Combined Team meeting on November 16, 2018. Exclusion criteria included involvement in the clinic's

CRC QI team or providers who did not attend the meeting. Of the 18 primary care providers at the meeting, only 14 completed a pre/post-test. The identity of those 14 providers is anonymous.

Medical Records

A total of 200 medical records were randomly selected from patients who were seen in clinic prior to the intervention between August 1, 2018 and October 31, 2018. Another 200 medical records were randomly selected from patients who were seen in clinic after the intervention between December 1, 2018 and February 28, 2019. Inclusion criteria were: persons 50 through 75 years of age; attending the primary care clinic only; seen as a Health Maintenance, Established Patient, or New Patient visit; seen by a primary care provider who attended November's Combined Team Meeting. Exclusion criteria included: not average-risk as defined by USPSTF; <50 years, >75 years; identified as a duplicate patient; or provider not in attendance at interventional November meeting**.**

Institutional Review Board Approval

An interprofessional training grant was approved by the affiliated university's Institutional Review Board (IRB). After IRB approval, the QI team was able to begin PDSA cycles and an individual project stemming from QI group work began.

Measures

A survey of knowledge, attitudes, and self-efficacy of Cologuard® was created by the PI and based on the ACS's Clinician's Reference and verbal presentation from the PI and QI lead-resident (see Appendices A and B). The survey was distributed to the providers for completion at the November meeting. The survey was the same for both the pre- and post- intervention period, and included five knowledge-based questions, five questions about attitudes, and five questions about self-efficacy. Additionally, the post-test included an optional line for comments.

The findings of the pre- and post- tests were scored based on correct answers for the knowledge-based questions (potential range 0-5, highest score = 5), and measured using a Likert scale for questions regarding attitudes (potential range 5-25, highest score = 25) and self-efficacy (potential range 5-25, highest score = 25).

Order rates of Cologuard® were collected from 200 randomly-selected charts of patients seen in clinic prior to November's intervention (August 1, 2018 – October 31, 2018), and 200 randomly-selected charts of patients seen after the intervention (December 1, 2018 – February 28, 2019) using sample inclusion and exclusion criteria. The results were stored in a Microsoft Excel spreadsheet. See Table 2 for summary of variables.

Data Collection

All study data were kept confidential and stored on the PI's personal password-protected computer with a secure server. Patient identifiers were not included in data sets. The first stage of data collection included distribution of pre- and post- tests to all 18 providers in attendance at the November meeting. The identity of the participating providers was anonymous. The 14 completed surveys were recollected, and paired pre- and post- test responses were then entered into Microsoft Excel by the PI.

The second stage of data collection involved chart reviews of patients who met inclusion criteria for the study. An electronic list was provided by a clinic staff member of all patients who met inclusion criteria for the months of August through October 2018. An online random number generator was used to provide 200 random numbers, which correlated to 200 persons on the numbered list of patients meeting inclusion criteria for the pre-intervention period. Of those 200 charts that were audited, 12 were excluded for the following reasons: provider participated on QI team; seen as a nurse visit or in department other than the primary care clinic; past medical

history of Crohn's disease; duplicate patient encounter. The random number generator was again used to provide 12 additional numbers in order to attain a total chart count of 200 patients. The following data for the pre-intervention period were entered into Microsoft Excel: correlating chart number; date of service; visit type; provider type; meets screening criteria (Y/N); CRC screening up to date (Y/N); colonoscopy ordered/scheduled (Y/N); Cologuard discussed (Y/N); Cologuard ordered (Y/N); Notes.

A similar process was repeated for the post-intervention chart review. An online number generator was again used to generate 200 random numbers that correlated with a numbered list of patients meeting inclusion criteria from December 2018 through February 2019. There were 23 charts excluded for the following reasons: provider participated on QI team; provider not in attendance at interventional meeting; patient less than 50 years of age; patient greater than 75 years of age. The online random number generator was used to produce 23 additional numbers. 200 charts for the post-intervention period were reviewed, and data were entered into Microsoft Excel using the same organizational headings from the pre-intervention period.

Data Analysis

Statistical analysis was completed using IBM SPSS statistical software version 24. Descriptive analysis was used to determine frequencies with percentages to describe nominal demographic variables. Differences between variables in the samples before and after the intervention were assessed using paired sample t-tests to assess changes in attitudes and self-efficacy, and McNemar's test for items on knowledge pre/post intervention. Variances in the proportion of Cologuard® ordering rates before and after the intervention were assessed using chi-square analyses.

Results

Demographics

Of the 18 primary care providers in attendance at the meeting, 14 completed pre- and post- tests. The ratio of male to female providers was even. Half of the providers in attendance were resident physicians. Most of the providers reported less than five years of experience. See Table 3 for provider demographics.

Provider Knowledge

Overall, provider knowledge increased after the educational intervention (see Figure 2). The average provider score prior to the education was 3.36 correct responses out of 5 items (SD=1.15). After the intervention, the average provider knowledge score was 4.71 correct responses out of 5 items (SD=0.61). McNemar's test showed a statistically significant difference in knowledge scores before and after the intervention ($p<0.001$) (see Table 4).

Provider Attitudes

The overall means score of provider attitudes increased from 19.41 out of a possible 25 points (SD=3.11) before the intervention to 20.64 out of a possible 25 points (SD=1.74) after the intervention. Though there was an increase in positive attitudes relating to Cologuard®, statistical analyses revealed that a change in provider attitudes pre- and post- intervention was not statistically significant ($p=0.142$) (see Table 4 and Figure 3).

Provider Self-Efficacy

Provider self-efficacy related to Cologuard® increased after the educational intervention. The overall mean for provider self-efficacy increased from 19.07 out of a possible 25 points in the pre-intervention period (SD=4.67) to a mean of 23.29 out of a possible 25 points in the post-

intervention period (SD=1.98). Thus, the change in self-efficacy from the pre- to post- test was statistically significant (p=0.002) (see Table 4 and Figure 4).

Order Rates of Cologuard®

Pre-Intervention

The PI performed a chart review of 200 randomly selected patients who met all inclusion criteria and for whom screening was indicated during the pre-intervention months of August through October 2018. Of those 200 patients, 151 (75.5%) had documentation in at least one place in the Electronic Health Record (EHR) of up-to-date CRC screening. The remaining 49 of 200 patients (24.5%) did not have documentation in the EHR to indicate CRC screening was current.

Of the 49 patients who were not up-to-date on screening, 31 (63.3%) did not have CRC screening ordered during the patient-provider encounter. Reasons for not ordering some modality of CRC screening included: patient refused, provider will discuss at subsequent visit, or no reason documented in EHR. Of the 49 patients without previously documented CRC screening, 18 (36.7%) had CRC screening ordered at the time of their clinic visit.

Of the 18 patients who had CRC screening orders placed during the pre-intervention period, 17 (94.4%) had colonoscopy orders placed, and Cologuard® was ordered for one patient (5.6%). See Figure 5 for comparison of order rates pre- and post- intervention.

Post-Intervention

The PI performed a chart review from 200 randomly selected patients who met all inclusion criteria and for whom screening was indicated during the post-intervention months of December 2018 through February 2019. Of those 200 patients, 142 (71%) had documentation in

at least one place in the EHR of up-to-date CRC screening. The remaining 58 of 200 patients (29%) did not have documentation in the EHR to indicate CRC screening was current.

Of the 58 patients who were not up-to-date on screening, 26 (44.8%) did not have CRC screening ordered during the patient-provider encounter. Reasons for not ordering some modality of CRC screening included: patient refused, provider will discuss at subsequent visit, or no reason documented in EHR. Of the 58 patients without previously documented CRC screening, 32 (55.2 %) had CRC screening ordered at the time of their clinic visit.

Of the 32 patients who had CRC screening orders placed during the post-intervention period, 27 (84.3%) had colonoscopy orders placed, 3 (9.4%) had fecal occult blood test (FOBT) ordered, and 2 (6.3%) had Cologuard® ordered. See Figure 5 for comparison of order rates pre- and post- intervention.

Finally, a chi-square test was used to analyze Cologuard® order rates for patients who were not up-to-date on CRC screening in the pre- and post- intervention periods. Analyses revealed x^2=0.193 and no statistically significant difference in Cologuard® order rates (p=0.660) from the pre- to post- intervention periods (see Table 5).

Barriers Identified

At the end of the post-test, providers were asked to leave additional comments explaining their answer. In doing so, the PI hoped to gain insight to potential barriers of Cologuard® use in practice and identify potential solutions moving forward. Eight out of 14 providers left comments.

Five providers commented there is no specific place to document Cologuard® within the EHR. Furthermore, many of these providers added there is no consistent place populated within the EHR to see if screening was completed or what the results were. Solutions to these barriers

included provider comments such as “create EHR result field for Cologuard” ; “in patient flowsheet where we document mammogram, eye exam, etc. make a column for Cologuard so it can easily be seen whether they have had it and when” ; “make a consistent location under same heading as colonoscopy.”

The following remarks represent perceived barriers of Cologuard® from providers in this clinic: “the form is a natural barrier like any paperwork in clinic” ; “time to complete order form – improving with my new CST as she is more involved” ; “a handout would help for patients literate enough, like main points on a card.”

Discussion

Influencing Knowledge, Attitudes, Self-Efficacy, and Order Rates

The use of a QI team is an effective way to identify problems within a setting, gain perspective from different disciplines, hypothesize potential solutions, and plan and execute practice improvement cycles with the aim of achieving a goal set by the QI group. In both collaborative and individual efforts, the QI group and PI at a large primary care clinic sought to improve variables related to Cologuard®, including provider knowledge, attitudes, self-efficacy, and order rates of Cologuard®.

A provider-based educational intervention improved provider knowledge and self-efficacy related to Cologuard® use in clinic. The intervention did not, however, change attitudes toward Cologuard® during the time period identified for this study. Though the overall mean for attitudes increased, the change was not statistically significant. Provider order rates of Cologuard® did not increase after the educational intervention.

The outcomes of this experiment are similar to other studies in the literature. Sheinfeld-Gorin et al. (2000) used a similar pre- and post- test design with an educational intervention.

The study concluded that there was a statistically significant difference in provider knowledge scores before and after the educational intervention ($p<0.001$). Additionally, barriers were identified and included in the discussion of the study (Sheinfeld-Gorin et al., 2000).

The study by Rim et al. (2009) revealed a strong association between provider knowledge and higher CRC screening rates ($p=0.02$), but no statistically significant correlation between attitudes, beliefs, and CRC screening practices. The results of the PI's study do not take into account overall screening rates in the pre- to post- intervention period. It would be interesting, however, to examine whether the findings of Rim et al. could be generalized by looking at overall screening (beyond just Cologuard®) in the PI's primary care clinic.

Application of Theory

This study supports the use of the TRA/TPB framework. One of the measures examined in the pre- and post- surveys was provider attitudes. Based on this theoretical framework, if an increase in attitudes will increase the likelihood of a behavior, then one can assume an increase in provider attitudes will lead to increased CRC screening by providers. It is important to note there was an increase in positive attitudes relating to Cologuard®, although it was not statistically significant (see Figure 3). The second concept of the TRA/TPB framework is subjective norms. This aspect is applicable because referent groups often share a commonality; the shared sample demographic was profession (primary care providers). In accordance to the TRA/TPB theory, a provider will be more likely to screen for CRC if he or she feels that his or her referent groups also support, utilize, and value CRC screening. Self-efficacy ties closely with behavioral control—or assumed ease versus difficulty of a behavior. This study revealed a statistically significant change in provider self-efficacy related to Cologuard® in the pre- and post- intervention periods.

Implications for Practice

Providers who offered written feedback after the intervention and post-test allowed for identification of barriers and possible solutions. One way to integrate results of this study into practice is to consider adding a clear, logical, and pre-populated field within the EHR to address Cologuard® orders and results. This step may alleviate or eliminate the provider from having to involve the nurse or CST in completing the paper order form, waiting for a fax or notification not otherwise tasked to the provider, or searching through the EHR to find if and when Cologuard® was completed.

Another implication for future practice includes the use of a provider portal as a means to potentially increase order rates and overall satisfaction with the ordering and result retrieval processes. Through the Cologuard® website, institutions can create an online portal for placing orders and reviewing results. Utilizing the provider portal could potentially address the issue of paper forms identified as a barrier by providers in this study. Orders placed electronically will be automatically uploaded onto the portal, and faxed order requests—this clinic's current procedure for ordering Cologuard®—will deliver results via both fax and online portal (Cologuard, 2018). Confirmation of orders and results are stored within the portal and can be easily accessed for a particular patient, reducing the need for providers to search the EHR or faxed results for this information.

Patient-based interventions could also address underutilization of Cologuard® for patients preferring non-invasive CRC screening. Examples of interventions that educate and empower the patient, rather than the provider, include: written materials (i.e. pamphlets, posters, or patient handouts), and providing the patient with access to health information on the internet (i.e. Cologuard® website or other evidence-based sites).

It is worthwhile to note the potential impact of provider-based interventions on certain measures. Because a statistically significant change was seen in provider knowledge and self-efficacy of Cologuard® in the post-intervention period, it may be beneficial to conduct educational sessions on other topics, such as various MACRA measures or weaker areas of practice, to boost knowledge, self-efficacy, and possibly provider attitudes towards those matters.

Implications for Further Study

The need to determine the reliability and validity of the provider survey is one important implication for further study, as the true reliability and validity remains unknown; if this cannot be achieved, consideration of a different validated survey may be warranted. It may also be useful to extend the time frame of the study to determine whether knowledge, attitudes, and self-efficacy were sustained over time. Finally, a multi-site design would be ideal to test replicability and generalizability of the study.

Limitations

Limitations of this study include a small sample size of providers (n=14) from which demographics, knowledge, attitudes, and self-efficacy were examined. A larger sample size would have been more ideal in order to measure more accurate variances in measures pre- and post- intervention. This was a single-center design over the course of a few months. Increasing the project to a multi-center study for a longer amount of time may help to generalize and compare outcomes. The reliability and validity of the pre- and post- test has not been determined, as it was generated by the PI and not trialed prior to this study. Additionally, data collected from the pre- and post- tests involve answers which may reflect responder bias.

Additional limitations include small sample sizes in both the pre- and post- intervention chart review phases. Although 200 charts were reviewed in both the pre- and post- periods, 151 out of 200 patients were up-to-date on screening recommendations in the pre-intervention phase. This left only 49 out of 200 patients needing CRC screening. Similarly in the chart review for patients seen after the intervention, only 58 patients did not have documentation of current CRC screening.

Conclusion

CRC is the third most prevalent cancer and second deadliest cancer in the U.S., with higher incidences in Kentucky than the majority of other states (CDC, 2017). Because most colorectal malignancies are slow-growing, CRC screening is vital in decreasing morbidity and mortality. Although CRC prevention tests—such as colonoscopy or flexible sigmoidoscopy—are the preferred screening modality, Cologuard® is a safe, non-invasive, and highly sensitive option for patients preferring stool-based screening tests (ACS, 2017a).

Quality improvement groups can be instrumental in identifying a problem in practice and working with various disciplines to improve upon that problem. In this study, a provider-based intervention stemming from both group and individual contributions was chosen to address the underutilization of Cologuard® in clinic. Presentation to clinic providers using the ACS's Clinician's Reference and an overview of the clinic's current procedures for ordering Cologuard® was chosen as the provider-based intervention. Pre- and post- tests revealed a statistically significant increase in provider knowledge and self-efficacy after the intervention. While differences in provider attitudes and order rates of Cologuard were not statistically significant, it is important to consider other implications for future practice, such as modifications to the EHR or use of Cologuard® portal, to increase those measures. This

initiative may provide necessary suggestions and first-steps to facilitate organizational changes that would lead to an increase in Cologuard® orders.

Appendix A. *Pre-test of Knowledge, Attitudes, and Self-Efficacy Related to Cologuard*

PRE-TEST

Your answers are anonymous.

I am a:

☐ Male ☐ Female
☐ Attending Physician ☐ Resident Physician ☐ Advanced Practice Provider
☐ Less than 5 years as provider ☐ Greater than 5 years as a provider
☐ Full-time employee ☐ Part-time employee

In order to maintain anonymity and match your pre-test and post-test, please select a random number with 3 or more digits. Remember this number and copy it onto the post-test.
Number: _____

---

1. Cologuard would not be an appropriate colorectal cancer (CRC) screening method for a patient with the following:
    a) Personal history of CRC
    b) Family history of CRC
    c) Personal history of adenomas
    d) Family history of hereditary colorectal cancer syndromes
    e) All of the above

2. Cologuard differs from other Fecal Immunochemical Tests (FIT) in that:
    a) Samples may be obtained by digital rectal exam (DRE)
    b) Positive results do not require a follow up colonoscopy
    c) It can be performed on a simple smear rather than an entire bowel movement
    d) It can detect increased levels of altered DNA biomarkers in stool
    e) Unsure

3. Based on current USPSTF recommendations, how often should Cologuard be repeated?
    a) Every 1 year
    b) Every 3 years
    c) Every 5 years
    d) Every 10 years
    e) Unsure

4. Correct Cologuard use requires a patient to collect how many stool samples?
    a) 2-3" smear
    b) 1
    c) 2
    d) 3
    e) Unsure

5. Medications and/or dietary choices may alter Cologuard results.
    a) True
    b) False
    c) Unsure

Please use the Likert Scale (1-5) to measure the following attitudes and beliefs:

Question	①=Strongly Disagree ②=Disagree ③=Neutral/Don't Know ④=Agree ⑤=Strongly Agree				
6. Cologuard is an effective CRC screening test.	1	2	3	4	5
7. I am likely to discuss Cologuard with patients for whom screening is indicated.	1	2	3	4	5
8. I am likely to order Cologuard for patients who prefer a stool-based test.	1	2	3	4	5
9. Documentation of Cologuard within the EHR is clear and consistent.	1	2	3	4	5
10. Barriers exist that prevent me from discussing and/ or ordering Cologuard in the primary care setting.	1	2	3	4	5
11. I am confident in my understanding of Cologuard as an emerging CRC screening test.	1	2	3	4	5
12. I am comfortable discussing Cologuard as a screening option with my patients.	1	2	3	4	5
13. I am confident in my understanding of the clinic's procedure for ordering Cologuard.	1	2	3	4	5
14. I am confident in my understanding of the clinic's procedure for obtaining Cologuard results.	1	2	3	4	5
15. It is easy to access resources and/or materials for Cologuard.	1	2	3	4	5

Appendix B. *Post-test of Knowledge, Attitudes, and Self-Efficacy Related to Cologuard*

POST-TEST

Your answers are anonymous.

In order maintain anonymity and match your pre-test and post-test, please recall the same randomly selected number that you wrote on your pre-test and copy the number below:
Number: _____

---

1. Cologuard would not be an appropriate colorectal cancer (CRC) screening method for a patient with the following:
    a) Personal history of CRC
    b) Family history of CRC
    c) Personal history of adenomas
    d) Family history of hereditary colorectal cancer syndromes
    e) All of the above

2. Cologuard differs from other Fecal Immunochemical Tests (FIT) in that:
    a) Samples may be obtained by digital rectal exam (DRE)
    b) Positive results do not require a follow up colonoscopy
    c) It can be performed on a simple smear rather than an entire bowel movement
    d) It can detect increased levels of altered DNA biomarkers in stool
    e) Unsure

3. Based on current USPSTF recommendations, how often should Cologuard be repeated?
    a) Every 1 year
    b) Every 3 years
    c) Every 5 years
    d) Every 10 years
    e) Unsure

4. Correct Cologuard use requires a patient to collect how many stool samples?
    a) 2-3" smear
    b) 1
    c) 2
    d) 3
    e) Unsure

5. Medications and/or dietary choices may alter Cologuard results.
    a) True
    b) False
    c) Unsure

Please use the Likert Scale (1-5) to measure the following attitudes and beliefs:

Question	①=Strongly Disagree ②=Disagree ③=Neutral/Don't Know ④=Agree ⑤=Strongly Agree				
6. Cologuard is an effective CRC screening test.	1	2	3	4	5
7. I am likely to discuss Cologuard with patients for whom screening is indicated.	1	2	3	4	5
8. I am likely to order Cologuard for patients who prefer a stool-based test.	1	2	3	4	5
9. Documentation of Cologuard within the EHR is clear and consistent.	1	2	3	4	5
10. Barriers exist that prevent me from discussing and/ or ordering Cologuard in the primary care setting.	1	2	3	4	5
11. I am confident in my understanding of Cologuard as an emerging CRC screening test.	1	2	3	4	5
12. I am comfortable discussing Cologuard as a screening option with my patients.	1	2	3	4	5
13. I am confident in my understanding of the clinic's procedure for ordering Cologuard.	1	2	3	4	5
14. I am confident in my understanding of the clinic's procedure for obtaining Cologuard results.	1	2	3	4	5
15. It is easy to access resources and/or materials for Cologuard.	1	2	3	4	5

If you answered 'Disagree' or 'Strongly Disagree' for Question # 9, please explain your answer and/or offer potential solutions:

_____
_____
_____
_____

If you answered 'Strongly Agree' or 'Agree' for Question # 10, please explain your answer and/or offer potential solutions:

_____
_____
_____
_____

Table 1. *Recommendations for Common CRC Screening Modalities*

Screening Modality	Screening Interval (Negative result)
CRC Prevention Test	
• Colonoscopy	Every 10 years
• Flexible sigmoidoscopy	Every 5 years
• CT colonography	Every 5 years
CRC Detection Test (Non-Invasive)	
• High-sensitivity FIT test (several brands)	Yearly
• High-sensitivity guaiac-based fecal occult blood test (Hemoccult Sensa)	Yearly
• FIT-DNA test (Cologuard®)	Every 3 years

(Rex et al., 2017)

Table 2. *Summary of Variables*

Variable	**Scoring Measure**	**Time-point of Measure**	**Level of Measure**	**Data Source**
Knowledge of Cologuard®	1-5 based on # correct	Pre and Post	Interval	Survey
Attitudes about Cologuard®	Likert scale	Pre and Post	Interval	Survey
Provider self-efficacy	Likert scale	Pre and Post	Interval	Survey
Cologuard® orders	Yes vs. No	Pre and Post	Nominal	Electronic Health Record

Variable	**Scoring measure**	**Timeline**	**Level of Measure**
Gender	Male vs Female	Baseline	Nominal
Type of Provider	Attending Physician Resident Physician APP (Nurse Practitioner or Physician's Assistant)	Baseline	Nominal
Experience of Provider	<5 years vs >5 years	Baseline	Nominal
Employment status	Full vs Part	Baseline	Nominal

Table 3. *Summary of Provider Demographics*

	n	*n*(%)
Providers in attendance	18	100%
Surveys completed	14	77.8%

Category	*n*	*n*(%)
Gender:		
Male	6	42.9%
Female	6	42.9%
Did not specify	2	14.2%
Type of Provider:		
Attending	5	35.7%
Resident	7	50.0%
APP	2	14.3%
Did not specify	0	0.0%
Years of Experience:		
<5 years	8	57.1%
>5 years	1	7.1%
Did not specify	5	35.7%
Employment Status:		
Full-time	9	64.3%
Part-time	0	0.0%
Did not specify	5	35.7%

Table 4. *Statistical Analyses of Provider Knowledge, Attitudes, and Self-Efficacy*

	Potential range	Pre-education *Mean* (SD)	Post-education *Mean* (SD)	*P*-value
Knowledge	0-5	3.36 (1.15)	4.71 (0.61)	<0.001 *
Attitudes	5-25	19.41 (3.11)	20.64 (1.74)	0.142
Self-efficacy	5-25	19.07 (4.67)	23.29 (1.98)	0.002 *

* denotes statistically significant data based on *p*-value <0.05

Table 5. *Statistical Analyses of Cologuard® Orders for Patients Not Up-To-Date with CRC Screening*

	Cologuard® ordered: YES	Cologuard® ordered: NO	Row Totals
Pre-Intervention	1 *(1.37)* [1.10]	48 *(47.63)* [0.00]	**49**
Post-Intervention	2 *(1.63)* [0.09]	56 *(56.37)* [0.00]	**58**
Column Totals	**3**	**104**	**107** (Grand Total)

x^2 = 0.193
P-value = 0.660
The result is *not* significant at $p < 0.05$.

Figure 2. *Percentage of Knowledge Questions Answered Correctly*

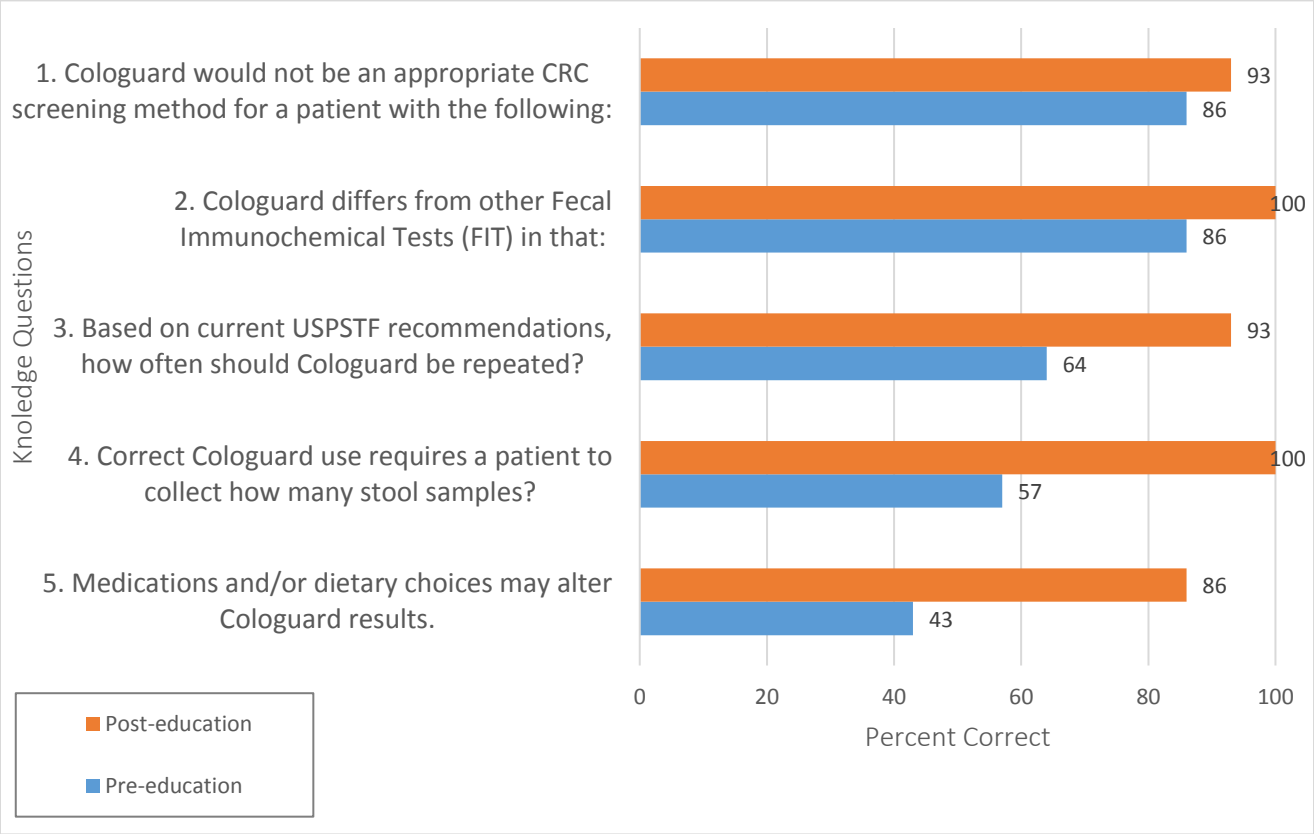


Figure 3. *Measurement of Provider Attitudes*

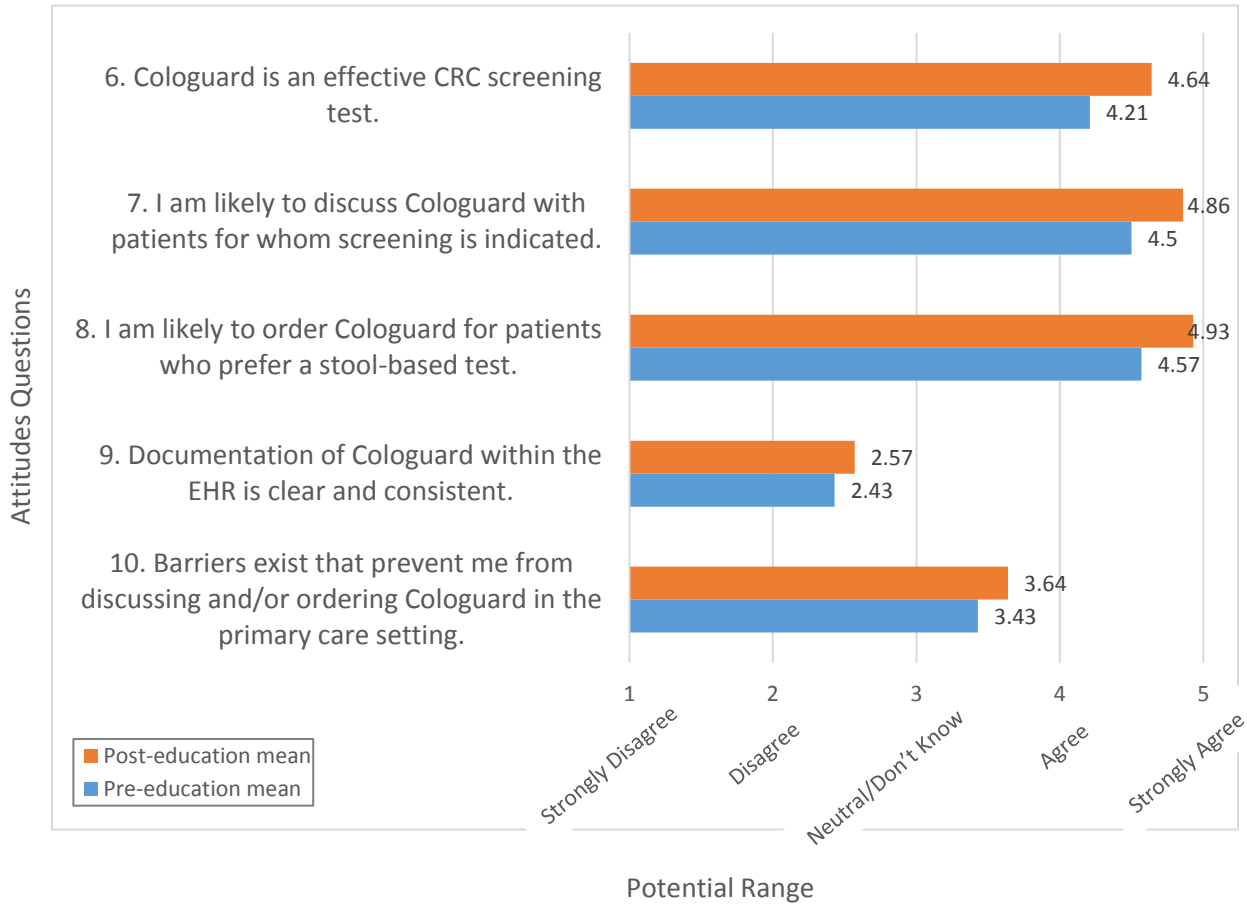


Figure 4. *Measurement of Provider Self-Efficacy*

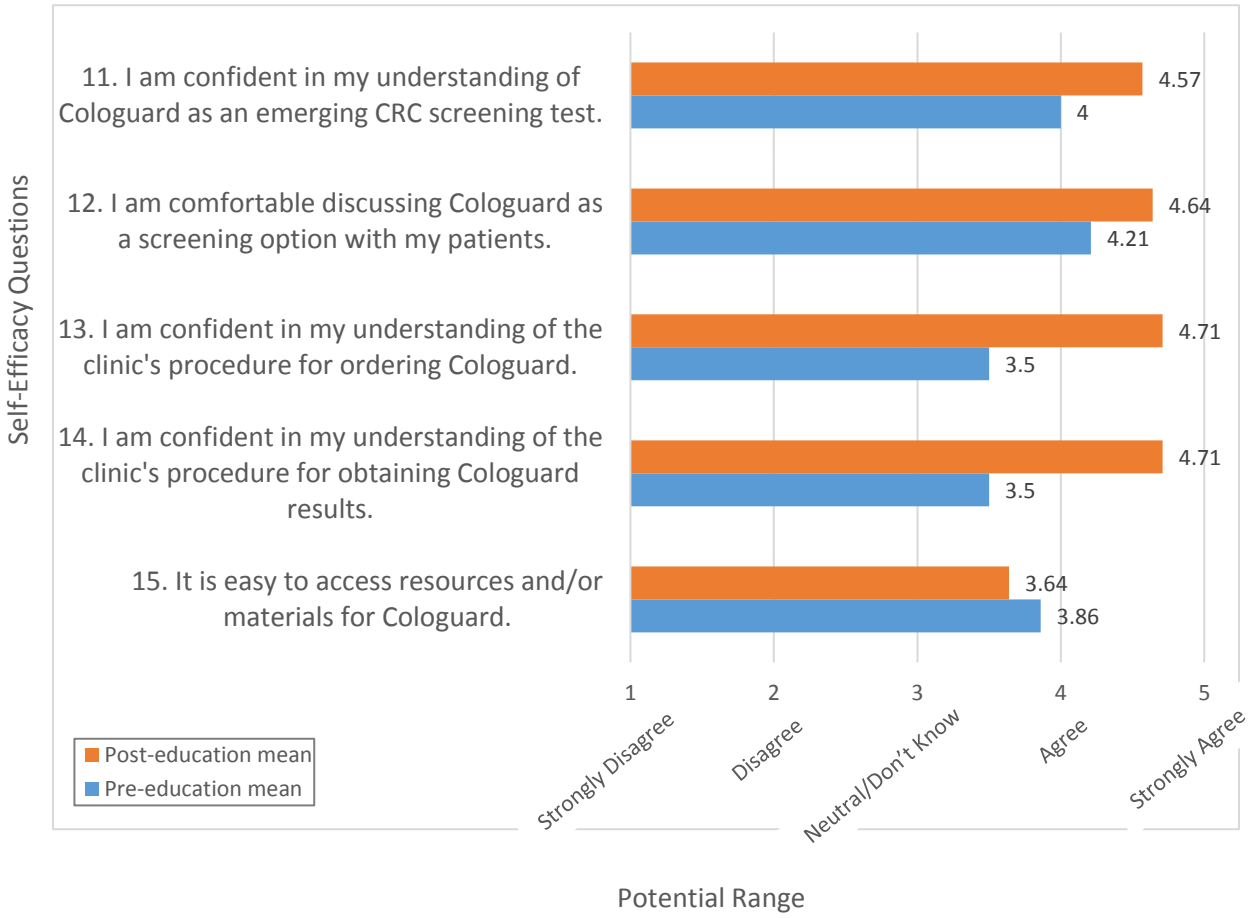
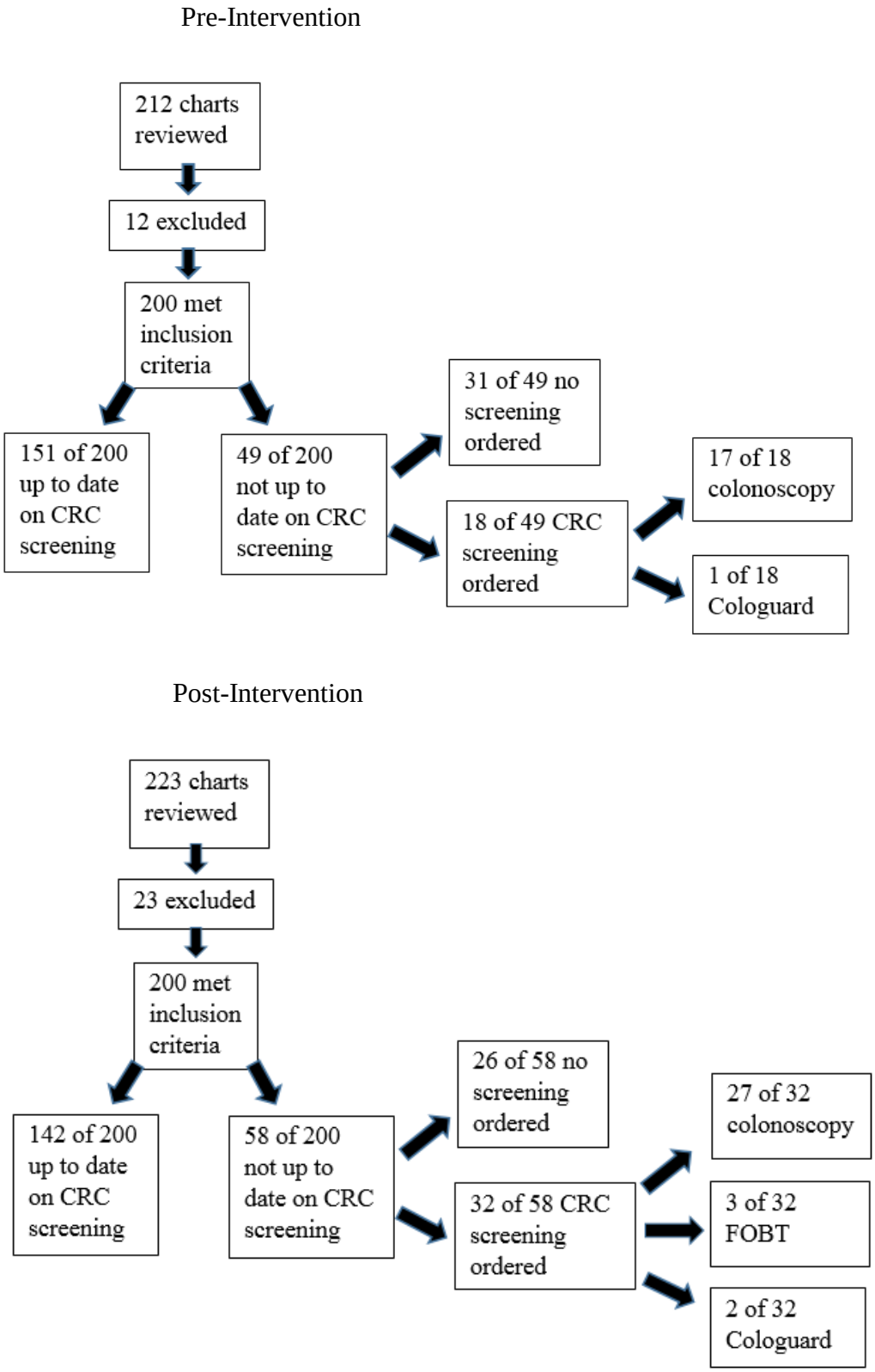


Figure 5. *Comparison of Cologuard® Order Rates Pre- and Post- Intervention*



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