

EDUCATING PRIMARY CARE PROVIDERS ON THE RECOMMENDED  
USE OF COLOGUARD

by

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As members of the DNP project Committee, we certify that we have read the DNP project prepared by Alexandra E. More, titled Educating Primary Care Providers on the Recommended Use of Cologuard and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

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## ABSTRACT

**Background:** In August of 2014, Cologuard was approved by the Food and Drug Administration (FDA) as a colorectal (CRC) screening method for average-risk adults. CRC is the second leading cause of cancer related deaths in the United States (US); therefore, it is extremely important to understand and be knowledgeable of how, when, and why Cologuard should be prescribed.

**Objective:** The purpose of this quality improvement (QI) project is to determine provider's knowledge of recommended national guidelines regarding Cologuard prescribing pre- and post-educational intervention.

**Design:** Quantitative study design is incorporated in the project, using a short multiple-choice pre- and post-survey and informational Cologuard brochure.

**Setting:** One rural primary care office in Safford, Arizona.

**Participants:** Primary care providers.

**Measurements:** Using measurements of central tendency with the results from the pre and post-survey.

**Results:** The overall results showed that participants (n=4) for the pre-survey revealed a mean score of 75% and participants (n=2) for the post-survey revealed a mean score of 84.62%. Three medical doctors and one nurse practitioner participated in the pre-survey and two medical doctors participated in the post-survey. One medical doctor participated in the post-survey twice due to not being able to find the brochure initially and the other medical doctor claimed he/she could not find the brochure; however, scores still improved by 9.62% from pre-survey to post-survey.

**Discussion:** The results of this QI project provided evidence that showed a change in provider knowledge regarding Cologuard use after evidence-based education using a brochure was provided. Although providers had knowledge previous to the educational intervention regarding Cologuard use, there is still a lack of knowledge among primary care providers regarding the national recommended guidelines and how and when to prescribe or not to prescribe Cologuard. Therefore, it is important for all primary care providers who prescribe Cologuard to be knowledgeable on current evidence-based recommendations provided by the US Preventative Service Task Force and Exact Sciences.

## INTRODUCTION

On August 11, 2014 the Food and Drug Administration (FDA) approved Cologuard testing as a method for screening for colorectal cancer (CRC) in average-risk adults ages 50 years old to 75 years old in age (U.S. Food & Drug Administration [FDA], 2019). Cologuard is a non-invasive stool-based test, prescribed to individuals, which checks for altered deoxyribonucleic acid (DNA) and/or blood that is shed from the intestinal lining and passed into stool (Cologuard, 2014). The test can be done in the privacy of the individuals own home, making this test sometimes a more attractive colon cancer screening method (Exact Sciences, 2016). An average-risk adult for screening colonoscopy includes adults with no family history or personal history of colon polyps, CRC, familial adenomatous polyposis (FAP), irritable bowel disease (IBD), ulcerative colitis (UC), Crohn's disease, or other related hereditary polyposis syndromes (Cologuard, 2014). Individuals and primary care providers prescribe Cologuard because there are no serious adverse risks, the test can be easier for patients to utilize, and for individuals who do not want to undergo other invasive procedures, they find Cologuard to be a more attractive alternative to CRC screening (Cologuard, 2014). Although patients and primary care providers may find Cologuard to be a more attractive alternative to screen for CRC, Cologuard has to be used and prescribed appropriately by primary care providers and gastroenterologists. Through personal clinical experience, the project investigator has found, many times in the city of Tucson, individuals are prescribed Cologuard and are considered high-risk for CRC. This is not only a misuse of the Cologuard test, but costly for the patient who will most likely have a positive Cologuard test and have to receive a diagnostic colonoscopy to rule out polyps or CRC. According to the United States Preventative Services Task Force (USPSTF)

(2016), Cologuard should be given every one to three years to average risk adults ages 50 to 75 years old. Unfortunately, not enough research and evidence is available regarding Cologuard misuse; therefore, reportable data for providers' Cologuard prescribing knowledge is not available at this time.

### **Problem Identification and Significance**

CRC is the second leading cause of cancer related deaths in the United States (US) and is the third most commonly diagnosed cancer among both genders (Siegel et al., 2017). According to the American Cancer Society (2018a) about 101,420 new cases of colon cancer will be diagnosed and about 44,180 new cases of rectal cancer will be diagnosed in the year 2019, leading to 51,020 CRC deaths. In a lifetime, 4.6% of men will be diagnosed with CRC (1:22), and 4.2% of women will be diagnosed with CRC (1:24), with the average age being 68 years old for males and 72 years old for females (American Cancer Society, 2014a). Colon cancers five-year survival rate is around 66%, and rectal cancers five-year survival rate is around 68%, where blacks are less likely to survive than whites (American Cancer Society, 2014a). CRC costs the US about \$14 billion dollars a year to treat, and an annual mean net cost of care per patient is about \$51,327 for females and \$51,812 for males (National Cancer Institute, 2011).

Methods for CRC screening should be considered based on every individual patient and screening options should be prescribed accurately based off recommended guidelines and patients personal or family history (Exact Sciences, 2016). CRC screening can be performed in many different ways; such as through colonoscopy, flexible sigmoidoscopy, fecal tests, and computed tomography (CT) colonography. A colonoscopy should be performed beginning at age 45 to 50 years old based on ethnicity and every 10 years if no abnormal findings or family

history of colon cancer or polyps exist (USPSTF, 2016). All other CRC screening exams have specific time intervals for when they should be used.

According to USPSTF (2016), fecal tests should be performed about every one to three years based on the stool test, whereas a CT colonography and flexible sigmoidoscopy should be performed about every five years, unless combined with another screening test, such as with a fecal immunochemical test. When Cologuard is accurately prescribed, the test has a sensitivity of 92.3% for detecting CRC (Song & Li, 2016). Cologuard can still produce false negatives and false positives within CRC screening patients; however, to achieve the most accurate results, primary care providers need to understand how Cologuard works and what patient populations are appropriate to utilize Cologuard. Positive Cologuard results are more likely to be seen in patients who have a personal or familial history of polyps, CRC, IBD, or other conditions increasing risk for CRC. Cologuard tests for altered DNA and/or blood in the stool, and individuals with a personal history or family history will most likely have altered DNA being shed in their stool, making a Cologuard screen less cost effective and inappropriate for these types of patients (Cologuard, 2014). Positive Cologuard results mean a recommended follow-up diagnostic colonoscopy exam (USPSTF, 2016). A colonoscopy screening procedure is a more appropriate screening method for high-risk patients to ensure high polyp or CRC detection rate (USPSTF, 2016). Most insurances typically cover CRC screening exams for individuals; however, diagnostic CRC exams cost additional fees based off deductibles and insurance plans (American Cancer Society, 2018b). This means if high-risk patients are inappropriately prescribed Cologuard, they will most likely end up paying more money for additional CRC screening exams.

### **Local Problem**

According to the Arizona Department of Health Services (2015), 2,475 invasive CRC cases were reported between the years 2008 to 2012, with an average annual rate for all ages being about 35.6 cases per 100,000 persons. Graham County has one of the highest incidence rates of CRC in the state of Arizona, and between the years 2008 to 2012, 45.8 cases per 100,000 were reported (Arizona Department of Health Services, 2015). If CRC is detected within early stages and polyps are removed in precancerous stages, the rate of morbidity and mortality could decrease. According to Nfonsam et al. (2015) incidence of CRC has decreased in the last three decades, rural counties in Arizona show a higher number of stage 4 CRC cases reported due to inadequate access to health care, lack of education regarding CRC screening, and lack of awareness. In Graham County, 18.6% of individuals are still uninsured and Nfonsam et al. (2015) found greater prevalence of CRC in rural areas. Rural areas of Arizona also tend to have an increased amount of biological, psychosocial, and chemical risk factors, which puts this population at greater risk for CRC (Nfonsam et al., 2015).

### **Needs Assessment**

A needs assessment identifies the gaps between what is occurring versus what should be occurring (White & Zaccagnini, 2017). In Safford, Arizona, the population has little access to CRC screening by means of colonoscopy; therefore, CRC rates are higher, and knowledge is limited (Nfonsam et al., 2015). Although primary care providers try their best to make CRC screening a priority, sometimes patients do not have access to transportation, nor the money to travel far to receive colonoscopy services. One rural primary care clinic involved in prioritizing CRC screening is Gila Valley Clinic in Safford, Arizona. The providers try to screen everyone

for CRC using mostly stool-based testing, even if not every single patient they see in their clinic is considered average-risk. The clinic president at Gila Valley Clinic in Safford, Arizona states that CRC is a high priority in their clinic and due to living in a rural area, they have a lot of experience with Cologuard and other stool-based CRC screening tests. Although, the test may not be utilized correctly in every patient, at least some form of CRC screening is taking place versus no screening at all. CRC at this clinic is considered a quality indicator and is reported every quarter. The clinic president does believe her providers are educated on Cologuard, but maybe they are not fully aware of all the contraindications for using Cologuard. Education for the providers would be appropriate at this time to help inform providers on the USPSTF recommendations for Cologuard use.

### **Purpose for Improvement**

The purpose for this quality improvement (QI) project was to educate providers at one Safford, Arizona primary care clinic on the recommended use of Cologuard screening for patients who qualify as average-risk individuals and assess provider knowledge for the recommended guidelines for Cologuard use before and after the educational brochure is reviewed. According to the USPSTF (2016) Cologuard should be given to average-risk adults, ages 50 to 75 years old every one to three years. The aim of the QI project was to increase primary care providers knowledge of the appropriate populations for Cologuard use by 30%. The outcome for this QI project was through education, primary care providers would have more knowledgeable regarding Cologuard prescribing and would understand high-risk individuals were not candidates for Cologuard, which should only be utilized in average-risk patients to avoid unnecessary additional screening methods, additional costs for patients, and decrease

anxiety among patients. The key stakeholders were primary care providers, which included medical doctors (MD's) and nurse practitioners (NP's) who had direct contact with patients and discussed CRC screening with their patient populations frequently, as well as patients who were due for CRC screening exams.

### **Patient-Centered Question (PICO)**

Can MD's and NP's at a rural primary care clinic in Safford, AZ (P) perceived knowledge regarding Cologuard guidelines, recommendations, and its use as a screening test among particular individuals ages 50 to 75 years old be increased (O) by an educational intervention using a brochure (I) compared to their perceived knowledge of this topic prior to the educational intervention (C)?

### **Theoretical Framework**

The Ottawa Model of Research Use (OMRU) was the theoretical approach guiding this DNP project. The OMRU is supported by evidence-based practice (EBP) research, expert opinions, and the use of theory to transfer knowledge into practice (Logan & Graham, 2011). The OMRU is comprised of elements aiding in the way research is applied and implemented into healthcare settings (Logan & Graham, 2011). These elements include the ability to adapt and adopt the change, to assess the project, to change attitudes, to increase awareness, to decrease barriers to project implementation, to address concerns in a culturally and socially acceptable manner, to consider economic outcomes, and to evaluate the outcomes (Logan & Graham, 2011). Assessment, monitoring, and evaluation (AME) methods are incorporated into the OMRU to help facilitate change within health care settings and aid in the implementation of QI (Logan & Graham, 2011).

The OMRU has been implemented in many research studies and QI projects due to the model's ability to transfer information in a systematic and effective manner (Logan & Graham, 2011). Katende and Donnelly (2016) incorporated the OMRU to educate nurses about the World Health Organization (WHO) recommendations regarding hypertension interventions in Uganda. The goal of the project was to address how management of hypertension is lacking in Uganda (Katende & Donnelly, 2016). The use of knowledge translation and education of WHO recommendations was implemented to promote increased knowledge, skills and attitudes for nurses managing hypertension in Uganda (Katende & Donnelly, 2016). The project investigator chose to incorporate the OMRU within this QI project to educate providers on the USPSTF recommendations regarding Cologuard prescribing, with the goal to improve patient outcomes. The OMRU helps QI projects implement education to aid in increased knowledge to transform practice and improve outcomes (Logan & Graham, 2011).

This DNP project focuses on educating providers on the recommended use of Cologuard screening for patients who qualify as average-risk individuals and then assessing provider knowledge for the recommended guidelines for Cologuard. Education for primary care providers and their patients is essential to help improve CRC screening and to help providers decide which CRC screening method is best for each and every patient population. Thorough assessment of an individual's health history, family history, and physical examination is important when deciding CRC screening options. Providing current research and EBP within healthcare helps providers understand why QI is important and why change should occur. To implement the OMRU, a guideline or recommendation should be low in complexity, compatible with current practice, and should be clear, concise, noncontroversial, and evidence based (Logan & Graham, 2011). The

elements of the OMRU were important for this project because it helped implement change within a primary care clinic in Safford, Arizona to facilitate better patient outcomes and increase provider knowledge. The goal of the OMRU was to transfer information to the Gila Valley Clinic with the use of evidence-based research and expert knowledge (Logan & Graham, 2011).

### **Concepts**

This DNP project focused on educating providers on the recommended use of Cologuard screening for patients who qualify as average-risk individuals and then assessed provider knowledge for the recommended guidelines for Cologuard. The concepts surrounding the OMRU include adaptability, adoption, attitudes, assessment, awareness, barrier management, concerns, culture/social, economic, and evaluation (Logan & Graham, 2011). Guided by OMRU, the DNP project first assessed provider knowledge regarding Cologuard prescribing. Utilizing evidence-based recommendations through education, this may have provided providers with the knowledge they needed to adapt and adopt the change within practice and create positive attitudes to make appropriate decisions towards prescribing Cologuard. Providing research and recommendations may have expanded awareness, helped decrease implementation barriers and concerns, as well as transformed the preconceived notions surrounding Cologuard. This gained knowledge may aid providers in making EBP decisions when prescribing Cologuard to their patients and potentially help decrease additional costs for patients.

### **Synthesis of Evidence**

#### **Review of Literature**

To gain more understanding of how Cologuard works, how accurate it is, if it is preferred compared to other CRC screening methods, whether it is cost-effective, and in what

patient populations it is best suited for, literature searches were conducted using Cumulative Index of Nursing and Allied Health Literature (CINAHL) and PubMed. The keyword Cologuard was used for the search. Inclusion criteria included published within the last five years, human species, and English language. These searches yielded 26 results. Articles were excluded if they did not relate to Cologuard or were not research articles. Ten research articles were retained and helped apply to this projects purpose (Table 1).

The research articles found within the literature search all compared fecal immunochemical test (FIT) with Cologuard or multi-target stool DNA (MT-sDNA) test and colonoscopy. The main goals for most of the research was to see whether or not MT-sDNA tests had greater sensitivity and specificity compared to alternative screening methods. Among the research findings, Cologuard was found to be superior compared to FIT. Colonoscopy is still considered the standard for CRC screening and was used to see if FIT and MT-sDNA testing was an alternative to testing for CRC or colorectal adenomas. Prince et al. (2017) found Cologuard has a higher sensitivity compared to FIT and can be used in patients who have been noncompliant with CRC screening. Among all the studies, average-risk adults were the individuals tested, and high-risk individuals were excluded from all research. This shows high-risk individuals should be referred for traditional CRC screening with colonoscopy, and average-risk individuals can use Cologuard testing if they do not wish to have a more invasive test.

This DNP project focused on educating providers on the recommended use of Cologuard screening for patients who qualify as average-risk individuals and then assessing provider knowledge for the recommended guidelines for Cologuard. The USPSTF (2016) has

recommended guidelines stating Cologuard and FIT, as well as other DNA or fecal occult blood tests should be used in average-risk adults. Van Lanschot et al. (2017) is evaluating the performance of FIT and Cologuard testing in Netherlands and according to their national guidelines, high-risk adults were excluded from the research studies. Knudsen et al. (2016), Redwood et al. (2016), and Park et al. (2017) found Cologuard was a superior CRC screening test compared to FIT, where colonoscopy still remains the most reliable screening method. Chablani et al. (2016) found when patients were adequately educated about CRC screening methods, 64.4% of study participants preferred colonoscopy and 31.1% of study participants preferred MT-sDNA.

### **Strengths**

Cologuard has revolutionized the way CRC screening can be performed across multiple patient populations, including rural areas or areas with individuals who are of lower socioeconomic status who lack the finances or resources to have a routine screening colonoscopy procedure. This test is a safe, noninvasive, and convenient test to help screen for CRC (Itzkowitz, 2015). For individuals who do not want to have a colonoscopy, Cologuard is the next best choice to detect precancerous and cancerous lesions within the colon. Cologuard has a sensitivity of 92.3% and a specificity of 86.6% (Brown, 2014), making this a superior test compared to other CRC screening modalities that test solely for hemoglobin in a patient's stool (Brown, 2014). Cologuard detects altered DNA and/or hemoglobin in the stool, which may suggest precancerous or cancerous lesions within the lining of the colon wall (Itzkowitz, 2015). What sets this test apart from other noninvasive CRC screening tests, Cologuard is the only exam that tests for altered DNA passed within the stool and not just blood (Itzkowitz,

2015). Because Cologuard is noninvasive and safe, CRC screening increases among the population and possibly higher detection of precancerous and cancerous lesions will occur (Itzkowitz, 2015).

Although Cologuard has been shown to be reliable, this method should not be used in high-risk patients, false positives can increase patient costs, and colonoscopy screening still has a sensitivity of about 95%, making this still the most reliable CRC screening test (Itzkowitz, 2015). Positive Cologuard results require a diagnostic exam conducted by a gastroenterologist, which insurance typically will not cover 100%, increasing overall cost for the patient (American Cancer Society, 2018b). If no cancer is detected by the Cologuard test, cost to treat cancer and surgical interventions in the long run is expensive (American Cancer Society, 2018). According to the USPSTF (2016) Cologuard screening should be performed every one to three years, which can also increase patient noncompliance.

### **Barriers**

The gap between which tests to choose for which patient population falls upon the knowledge of the practitioner. If a patient refuses to have a colonoscopy for CRC screening, Cologuard is the second most appropriate test to choose because it tests both for blood and/or altered DNA (Cologuard, 2014). However, this test is not appropriate for some patient populations due to their higher risk for CRC and the potential increase in false positives, as well as increased patient costs. The goal for CRC screening is to provide a service that is reliable, prevents disease, and cost beneficial for patients and the healthcare system. Patients need to be aware of all the facts regarding both colonoscopy procedures as well as the risks of using Cologuard and what the results can mean. Healthcare providers who prescribe or

recommend screening exams need to obtain full health histories regarding personal and family history and understand what screening options are best for which patient. It is imperative practitioners understand what they are prescribing and how they are prescribing the test to help increase precancerous and cancerous lesions early enough to decrease morbidity and mortality.

### **Conclusion**

Cologuard is a new concept in the world of CRC screening, and additional research is needed to determine further patient population utilization. It may take additional research and advancements in MT-sDNA tests before this method can be utilized within all patient populations, including high-risk individuals.

TABLE 1. *Synthesis of evidence.*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
<p>Chablani, S.V., Cohen, N., White, D., Itzkowitz, S.H., DuHamel, K., &amp; Jandorf, L. (2016). Colorectal cancer screening preferences among Black and Latino primary care patients. <i>Journal of Immigrant and Minority Health, 19</i>, 1100-1108. doi:10.1007/s10903-016-0453-8</p>	<p>Assess preference for CRC screening (FIT, CT colonography (CTC), Cologuard, or colonoscopy) among blacks, English-speaking Latinos, and Spanish-speaking Latinos. Describe the attributes of the tests that influence preferences, assess the strength of their preference, and to determine in preference is associated with background knowledge of CRC, CRC screening history, or sociodemographic characteristics (Chablani et al., 2016, p. 1101).</p>	<p>Cross-Sectional</p>	<p><b>Sample:</b> Average-risk, asymptomatic English and/or Spanish-speaking black and Latino individuals between the ages of 50 and 74 years old who had undergone screening colonoscopy within the past 5 years.</p> <p>N=86 Mean age: 62.4 years old Female: N=60 Male: 26 Black: N=28 English-speaking Latino: N=29 Spanish-speaking Latino: N=29</p> <p><b>Setting:</b> The primary clinic at The Mount Sinai Hospital in New York City.</p>	<p><b>Data Collection:</b> A cross-sectional survey was conducted from March to April of 2015. Participants were recruited in the clinic waiting room with an IRB-approved flyer that was in English and Spanish. The survey involved a 20 to 30-minute three-part interview with health educators. The first component was a pre-education survey regarding the subject's socio-demographic and background knowledge of CRC and CRC screening history. The second component included education about CRC and CRC screening tests with print materials. The third component was a post-education survey to assess CRC screening test preference, attributes that influenced decision, and the</p>	<p>After being educated about the four screening tests, 58 (64.4%) participants preferred colonoscopy, 28 (31.1%) preferred Cologuard, 2 (2.2%) preferred CTC, and 2 (2.2%) preferred FIT.</p>

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
				<p>strength of the preference.</p> <p><b>Data Analysis:</b> Using SPSS version 22, statistical calculations were performed. Missing data was excluded from the analysis, categorical data was analyzed using Chi square analysis, and continuous data was analyzed by Student's <i>t</i> test. Significant variables in the univariate analysis were included using the multivariate logistic regression model predicting screening test preference.</p>	
<p>Cotter, T.G., Burger, K.N., Devens, M.E., Simonson, J.A., Lowrie, K.L., ..., Kisiel, J.B. (2016). Long-term follow-up of patients having false positive multi-target stool DNA tests after</p>	<p>To determine if false positive patients are at increased long-term risk for adverse outcomes.</p>	<p>Mixed Methods</p>	<p><b>Sample:</b> N=1,050</p> <p>Study 1 “Specificity” for average-risk for CRC between February 2010 and August 2010 (cross-sectional): N=485</p>	<p><b>Data Collection:</b> An Accurant database (LexisNexis) search was conducted to determine patients’ vital status. Patients or next of kin were then invited by mail for a structured telephone</p>	<p>MT-sDNA was FP in 113 (11%) and 51 (5%) patients at 90<sup>th</sup> and 95<sup>th</sup> percentile threshold (not statistically significant).</p> <p>Eight aerodigestive (lung and</p>

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
<p>negative screening colonoscopy: The long-haul cohort study. <i>Cancer, Epidemiology, Biomarkers &amp; Prevention</i>, 26(4), 614-621. doi:10.1158/1055-9965</p>			<p>Study 2 “Cutoff” higher-risk patients referred for known colorectal neoplasia and asymptomatic average-risk control patients who were scheduled for screening at the time of study enrollment between August 2011 and December 2011 (case-control): N=228</p> <p>Study 3 “DeeP-C” for average-risk patients who were scheduled for screening colonoscopy at the time of study enrollment between June 2011 and November 2012 (cross-sectional cohort): N=337</p> <p>Mean age: 65.6 Female: N=563 Male: N=487</p> <p><b>Setting:</b> Mayo Clinics (Rochester, MN, Scottsdale, AZ, and</p>	<p>interview to document new cancer or precancer diagnoses, the development of alarm symptoms, and subsequent EGD or colonoscopy results. Chart reviews were performed for all of those who declined the interview, for those who did not answer, and on random individuals who were interviewed to report potential bias.</p> <p><b>Data Analysis:</b> Assuming MT-sDNA test specificity of 90%, 850 patients were anticipated to provide 80% power to detect a difference between a 6% cumulative event rate in the false positive (FP) group from a 1% event rate in the true negative (TN) group, at 5% significance level. Kaplan-Meier method was used to assess rates</p>	<p>gastrointestinal tract) cancers occurred.</p> <p>FP was calibrated, but no per-protocol, cutoffs was associated with subsequent aerodigestive cancers.</p> <p>FP status was not associated with mortality or alarm symptoms.</p>

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
			Jacksonville, FL)	of mortality, subsequent cancer diagnosis, development of alarm symptoms, and subsequent aerodigestive cancer diagnosis. FP and TN were compared using 95% confidence interval was used as well as hazard ratios, and the expected Surveillance, Epidemiology, and End Results (SEER) Program cumulative incidence. Differences of patients were assessed using Fisher exact, Wilcoxon rank-sum tests, and $\chi^2$	
Cyhaniuk, A. & Coombes, M.E. (2016). Longitudinal adherence to colorectal cancer screening guidelines. <i>The American Journal of Managed Care</i> , 22(2), 105-111. doi:10.1158/1055-9965	“To describe adherence with the USPSTF CRC screening recommendations over a 10-year period, in a large, continuously insured population at average risk for CRC” (Cyhaniuk & Coombes, 2016, p. 105).	Retrospective Claims Database Analysis	<b>Sample:</b> Average-risk insured members who turned 50 years old between January 1, 2000 and December 31, 2004 and were of average-risk for CRC.  N=151,638 Male: N=71,832	<b>Data Collection:</b> A retrospective analysis of patient-level data from a large, national US administrative health claims database (Clinformatics DataMart, affiliated with Optum) containing records for	Of the 151,638 subjects, only 97,518 (64%) were adherent with current CRC screening recommendation.  18,050 (12%) individuals were considered inadequately screened.

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
			Female: N=79,806  <b>Setting:</b> US database analysis	medical pharmacy and laboratory services.  <b>Data Analysis:</b> Subject characteristics were analyzed descriptively using <i>t</i> tests for continuous variables and $\chi^2$ tests for dichotomous variables. Mean, and median was computed for all outcomes. Data analysis was generated using SAS version 9.2.	36,070 (24%) individuals were screening naïve.  Average age for beginning CRC screening was 53 years old (3 years past recommended guidelines).
Imperiale, T.F., Ransohoff, D.F., Itzkowitz, S.H., Levin, T.R., Lavin, P., ..., Berger, B.B. (2014). Multitarget stool DNA testing for colorectal-cancer screening. <i>The New England Journal of Medicine</i> , 370(14), 1287-1297. doi:10.1056/NEJMoal1311194	“The primary aim was to determine the performance characteristics of the DNA test in the detection of CRC. The second aim was to determine the performance of the multi-target stool DNA (MT-sDNA) test in the detection of advanced precancerous lesions and to compare it with a commercially available fecal immunochemical test	Cross-Sectional	<b>Sample:</b> 9989 males and females, ages 50-84 years old who were considered average-risk for CRC and who were scheduled for a screening colonoscopy.  Exclusion Criteria: personal history of colorectal neoplasia, digestive cancer, IBD, had undergone a colonoscopy in the last 9 years, barium enema CT colonography, or	<b>Data Collection:</b> All participants were required to provide a stool sample 90 days prior to their screening colonoscopy. Stool samples were homogenized, separated into aliquots, and frozen at -80°C on receipt. Stool aliquots were randomly sent to one of the three laboratories.  <b>Data Analysis:</b> All 9989 participants	Of the 9989 participants, 65 (0.7%) had CRC and 757 (7.6%) had advanced precancerous lesions on colonoscopy exam.  DNA versus FIT Sensitivity for CRC: 92.3% and 73.8% (P=0.002)  DNA versus FIT Sensitivity for Advanced Precancerous Lesions: 42.4% and 23.8% )

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
	(FIT) for human hemoglobin in the detection of both CRC and advanced precancerous lesions” (Imperiale et al., 2014, p. 1288).		<p>sigmoidoscopy in the last 5 years, had positive results from fecal blood testing within the last 6 months, had rectal bleeding in the last 30 days, had undergone a colorectal resection for any other reason other than sigmoid diverticula, had a personal or family history of CRC, had participated in any interventional clinical study in the last 30 days, or were unwilling to provide written informed consent.</p> <p><b>Setting:</b> Stool samples were sent to Exact Sciences (Madison, WI), Mayo Medical Laboratory (Rochester, MN), and Molecular Pathology Laboratory Network (Knoxville, TN). 90 different sites were used for colonoscopy procedure.</p>	had a colonoscopy performed and stool samples were both tested using a MT-sDNA and FIT. Each test compared sensitivity and specificity	(P<0.001)  DNA versus FIT Specificity: 86.6% and 94.9% (P<0.001)

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
<p>Johnson, D.H., Kisiel, J.B., Burger, B.S., Mahoney, D.W., Devens, M.E., ..., Sweetser, S. (2017). Multitarget stool DNA test: Clinical performance and impact on yield and quality of colonoscopy for colorectal screening. <i>Gastrointestinal Endoscopy</i>, 85(3), 657-665. doi:10.1016/j.gie.2016.11.012</p>	<p>The impact a positive MT-sDNA tests result has on colonoscopy yield and quality (Johnson et al., 2017, p. 657).</p>	<p>Randomized Control Trial</p>	<p><b>Sample:</b> Two cohort groups. First cohort retrospectively identified patients who had underwent colonoscopy at Mayo Clinic in Rochester, MN for the indication of positive MT-sDNA test administered for average risk individuals. Second cohort included the subset of patients with a positive MT-sDNA test during participation in a multicenter preapproval screening study.</p> <p>Unblinded Cohort: N=1908 Unblinded Analysis: N=172 Median Age: 69 years Male: N=65 Female: N=107</p> <p>Blinded Cohort: N=445 Blinded Analysis:</p>	<p><b>Data Collection:</b> A single examiner reviewed patient records and entered the information into a secure database that was centralized. Quality of preparation, non-neoplastic and neoplastic findings, and withdrawal time was all abstracted from the endoscopy reports. Pathology and histology findings were obtained.</p> <p><b>Data Analysis:</b> Assuming equal sizes, approximately 95 patients in each of the blinded and unblinded groups provided 80% power to demonstrate 20% difference in adenomatous colorectal neoplasia detection in a 2-sided test at the 5% significance level. Differences in baseline characteristics were assessed by the Wilcoxon rank sum test</p>	<p>Unblinded Cohort: 172 positive MT-sDNA tests.</p> <p>Blinded Cohort: 72 positive MT-sDNA tests.</p> <p>Median withdrawal time increased with unblinded group (19 minutes compared to 13 minutes, P=0.0001).</p> <p>70%(unblinded) compared to 53% (blinded) (P=0.013) for total adenomatous/sessile serrated polyps.</p> <p>28%(unblinded) compared to 21% (blinded) (P=0.27) for advanced neoplasms.</p>

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
			<p>N=72 Median Age: 70 years old Male: N=33 Female: N=39</p> <p><b>Setting:</b> Mayo Clinics (Rochester, MN, Scottsdale, AZ, and Jacksonville, FL)</p>	<p>for continuous variables. Proportions were assessed by the Fisher exact test and the <math>\chi^2</math>.</p>	
<p>Knudsen, A.B., Zauber, A.G., Rutter, C.M., Naber, S.K., Doria-Rose, V.P., ..., Kuntz, K.M. (2016). Estimation of benefits, burden, and harms of colorectal cancer screening strategies: Modeling study for the US preventative services task force. <i>The Journal of the American Medical Association</i>, 315(23), 2595-2609. doi:10.1001/jama.2016.6828</p>	<p>To identify the optimal age to begin and end screening, to identify a of model recommendable strategies that provide similar life-years gained, and a comparable balance between life-years gained and screening burden (Knudsen et al., 2016, p. 2595).</p>	<p>Modeling Study</p>	<p><b>Design, Setting and Participants:</b> Comparative modeling with three microsimulation models of hypothetical cohort of previously unscreened United States individuals aged 40 years old with no CRC.</p>	<p><b>Main Outcomes:</b> Lifetime number of colonoscopy complications, life-years gained compared with no screening, lifetime number of colonoscopies required, and the ratios of incremental burden and benefit per 1,000.</p> <p><b>Data Analysis:</b> To compare eight CRC screening modalities with one another and determine recommended guidelines.</p>	<p>Harm from screening: 23 per 1,000 persons screened.</p> <p>Colonoscopy every 10 years, annual FIT, sigmoidoscopy every 10 years with annual FIT, CTC every 5 years and annual FIT.</p> <p>Screening age for average risk: 50 years old to 75 years old.</p> <p>Limited empirical data for life-years gained from beginning screening at age 45 years old.</p>

TABEL 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
<p>Park, S., Baek, H.L., Yu, J., Kim, J.Y., Yang, H., ..., Park, D. (2017). Is methylation analysis of SFRP2, TFP12, NDRG4, and BMP3 promoters suitable for colorectal cancer screening in the Korean population? <i>Intestinal Research</i>, 15(4), 495-501. doi:10.5217/ir.2017.15.4.495</p>	<p>To validate that Cologuard's use of DNA markers for detecting CRC and colorectal advanced adenomas is effective in the Korean population.</p>	<p>Cohort Study</p>	<p><b>Sample:</b> N=111</p> <p>CRC: N=35 (Average age: 60.6 years old)</p> <p>Colorectal Advanced Adenomas: N=36 (Average age: 63.2 years old)</p> <p>Healthy Controls: N=40 (Average age: 55.7 years old)</p> <p><b>Setting:</b> Kangbuk Samsung Hospital</p>	<p><b>Data Collection:</b> Stool samples were obtained a day prior to colonoscopy from all 111 participants. Samples were randomly assigned to be DNA isolated or serve as a negative control. All tests were performed twice to validate results.</p> <p><b>Data Analysis:</b> Continuous variables were expressed as mean±SD and comparisons between groups were performed using one-way ANOVA. Variables not normally distributed were compared using Kruskal-Wallis test. Categorical variables were expressed as percentages, and comparisons between groups were performed using chi-square test. The sensitivity and specificity (including 95% CI) of the stool</p>	<p>Methylated <i>SFRP2</i>, <i>TFPI2</i>, <i>NDRG4</i>, and <i>BMP3</i> promoters were detected in 60.0%, 31.4%, 68.8%, and 40.0% of CRC samples and in 27.8%, 27.8%, 27.8%, and 33.3% of colorectal advanced adenoma samples, respectively.</p> <p>The sensitivities obtained using 4 markers to detect CRC and colorectal advanced adenoma were 94.3% and 72.2%, respectively.</p> <p>The specificity was 55.0%.</p>

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
				DNA assay were calculated using a manual method. <i>P</i> -values <0.05 were considered significant. All data analyses were performed using SPSS version 18.0.	
Prince, M., Lester, L., Chiniwala, R. & Berger, B. (2017). Multitarget stool DNA tests increases colorectal cancer screening among previously noncompliant Medicare patients. <i>World Journal of Gastroenterology</i> , 23(3), 464-471. doi:10.3748/wjg.v23.i3.464	“To determine the uptake of noninvasive multitarget stool DNA (mt-sDNA) in a cohort of CRC screening non-compliant average-risk Medicare patients” (Prince et al., 2017, p. 464).	Cross-Sectional	<p><b>Sample:</b> 347 average-risk noncompliant Medicare patients ages 50-85 years old. Mean age: 69.8 years old Females: N=222 (64%) Males: N=125 (36%)</p> <p><b>Setting:</b> USMD Physician Services, Dallas, TX.</p>	<p><b>Data Collection:</b> Over a 12-month (October 2014 to September 2015) period, 77 providers ordered 393 MT-sDNA studies for average-risk noncompliant Medicare patients. Investigators performed a Health Insurance Portability and Accountability Act compliant retrospective review of electronic health records to identify MT-sDNA use in patients who were either &gt;10 years since last colonoscopy and/or &gt;1 year since fecal occult blood test. All individuals with positive MT-sDNA tests were advised to</p>	<p>Of the 393 patients prescribed Cologuard, only 347 patients completed the test (88.3% compliance).</p> <p>MT-sDNA: negative in 85.3% (296/347) and positive in 14.7% (51/347).</p> <p>Follow-up colonoscopy: 49 positive patients (86.1%).</p> <p>Colon Cancer: 8.2% (4/49).</p> <p>Advanced Neoplasia: 42.9% (21/49).</p> <p>Non-Advanced Adenomas: 30.6%</p>

TABEL 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
				<p>have a follow-up diagnostic colonoscopy.</p> <p><b>Data Analysis:</b> Colonoscopy and pathology findings for MT-sDNA positive patients were tabulated and included: size, location, histologic classification, and total number of adenomas and non-adenomatous polyps. All high-risk patients were excluded from the study (symptomatic and/or significant personal or family history of colorectal neoplasia or IBD).</p>	<p>(15/49).</p> <p>Negative Results: 18.4% (9/49).</p> <p>MT-sDNA provided medical benefit to screening noncompliant Medicare patients. MT-sDNA identified clinically critical advanced colorectal neoplasia.</p>
<p>Redwood, D.G., Asay, E.D., Blake, I.D., Sacco, P.E., Christensen, C.M., ..., Ahlquist, D.A. (2016). Stool DNA testing for screening detection of colorectal neoplasia in Alaska native people. <i>Mayo Clinic</i></p>	<p>To assess the accuracy of a Cologuard compared to FIT for detection of colorectal neoplasia in Alaska Native people.</p>	<p>Prospective, Cross-Sectional</p>	<p><b>Sample:</b> Asymptomatic, Alaska Native adults ages 40-85 years or older who are undergoing screening or surveillance colonoscopy.</p> <p>N=661</p>	<p><b>Data Collection:</b> Two stool samples were collected from each participant prior to colonoscopy procedure. One stool test was tested using FIT and the other was tested using Cologuard. All colonoscopies were</p>	<p>A total of 868 participants were enrolled, where 661 participants completed the study.</p> <p>Screening-relevant colorectal neoplasia (SRN) for Cologuard: 49%</p>

TABEL 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
<p><i>Proceedings</i>, 91(1), 61-70. doi:10.1016/j.mayocp.2015.10.008</p>			<p>Females: N=403 Males: N=258 Median age: 55 years old</p> <p><b>Setting:</b> Alaska Native Medical Center (ANMC), Anchorage, Alaska</p> <p>Stool samples were sent to Mayo Clinic in Rochester, MN.</p>	<p>performed at ANMC by certified Endoscopists who were blinded to the stool sample results</p> <p><b>Data Analysis:</b> Powered at the 80% level to detect a difference in sensitivities of at least 20% between Cologuard and FIT assuming a 2-sided significance level of 5%.</p>	<p>SRN for FIT: 28% (P&gt;0.001)</p> <p>SRN detection for Cologuard: 50%</p> <p>SRN detection for FIT: 31% (P=0.01)</p> <p>CRC detection for Cologuard: 100%</p> <p>CRC detection for FIT: 80% (P=0.48)</p>
<p>van Lanschot, M.C.J., Carvalho, B., Coupé, V.M.H., van Engeland, M., Deller, E., &amp; Meijer, G.A. (2017). Molecular stool testing as an alternative for surveillance colonoscopy: A cross-sectional cohort study. <i>BioMed Central</i>, 17, 1-8. doi:10.1186/s12885-017-3078-y</p>	<p>To evaluate the performance of Cologuard in post-polypectomy, CRC, and familial colorectal cancer (FCC) compared to colonoscopy, FIT, and fecal occult blood test.</p>	<p>Cross-Sectional Cohort Study</p>	<p><b>Sample:</b> N=4,000</p> <p>Average risk adults, ages 50 to 75 years old.</p> <p><b>Setting:</b> Multi-center, cross-sectional cohort study in the Netherlands</p>	<p><b>Data Collection:</b> Clinical data assessing age, sex, indication and date of current surveillance colonoscopy, recommended surveillance interval and findings of previous colonoscopies. All information is collected and placed in a database. Stool samples were collected two to three weeks prior to colonoscopy</p>	<p>Study still in progress. No results have been yielded.</p>

TABLE 1 – *Continued*

Reference	Research Question/Hypothesis	Study Design	Sample and Setting	Methods for Data Collection and Data Analysis	Findings
				<p>examination.</p> <p><b>Data Analysis:</b>  This study will yield estimates for relative sensitivity and specificity of Cologuard and FIT versus colonoscopy. The analyses will be based on data from all participants who had valid results on Cologuard and/or FIT and colonoscopy. In case of missing values on outcome variables, the patient will be excluded. Exact binomial confidence intervals will be calculated around relative sensitivity, relative specificity, positive and negative predictive values.</p>	

## **METHODS**

### **Design**

The DNP project followed a quantitative approach, where a series of multiple-choice questions were asked to determine knowledge of Cologuard use pre- and post-intervention. The purpose of quantitative study methods is to determine if the data collected supports the QI project purpose (White & Zaccagnini, 2017). The quantitative information helped determine if the education intervention was effective.

### **Ethical Considerations**

The most common ethical principles to consider when implementing a QI initiative are persons, justice, and beneficence, which are vital to consider. Federal regulations for research involving human subjects must be reviewed by an institutional review board (IRB) or a research review board (RRB) (Eldridge, 2017). This QI activity did not involve human subjects; however, per protocol, review by the University of Arizona's IRB was received (see Appendix A).

### **Respect for Persons**

According to The Belmont Report (1979) respect for persons incorporates at least two ethical considerations, including individuals with diminished autonomy be entitled to protection and all individuals be treated as autonomous agents. To ensure this happens, informed consent is a requirement from all human subjects to give them the opportunity to choose what can or cannot happen to them in research (The Belmont Report, 1979). For individuals who are not able to make that decision for themselves because of incapacitation or immaturity, exclusion from such acts may occur and will have to be reevaluated constantly to prevent harm (The Belmont Report, 1979). Participants who are able to choose to participate in a study must do so without coercion

or pressure and education about what the research study entails is key (The Belmont Report, 1979). This QI project was not research, but participants were fully informed about the QI project with a disclosure form (see Appendix B).

The data collected by the project investigator targeted primary care providers who were able to prescribe Cologuard to patients. To protect their autonomy, it was imperative to explain the nature of the project with the disclosure form, to inform them their responses were to be completed anonymously, and to also inform them their participation was voluntary.

### **Justice**

All participants within a QI study should be treated equally and must all have their privacy maintained (The Belmont Report, 1979). This means all individuals are to be given the same information regarding project outcomes to ensure all participants do not know more than another participant during the study. It is important participants are invited based off what is being directly studied, rather than by easy availability, manipulability, or compromised position (The Belmont Report, 1979).

All participants in the study were given the same pre- and post- multiple-choice surveys and information brochure. The disclosure form described confidentiality and privacy concerns along with the project investigator's contact information to help providers ask questions regarding what this meant and how it would protect their identity.

### **Beneficence**

Beneficence is treating individuals in an ethical manner by protecting them from harm, as well as respecting their decisions (The Belmont Report, 1979). The two general rules surrounding beneficence are to do no harm while increasing possible benefits and decreasing

possible harms (The Belmont Report, 1979). By providing Cologuard information to providers, the potential for harm is greatly minimized. This DNP project focuses on educating providers on the recommended use of Cologuard screening for patients who qualify as average-risk individuals and then assessing provider knowledge for the recommended guidelines for Cologuard. Knowledge and information may help increase compliance with national recommended guidelines. Another consideration was, if providers choose to prescribe Cologuard based off of what they already know or how they conduct their practice, this must be respected.

### **Setting**

This project took place at Gila Valley Clinic, which is a rural primary care office in Safford, Arizona. Site approval was given to the project investigator by the president of Gila Valley Clinic (see Appendix C). This primary care office is a rural community in Safford, Arizona and serves all ages and genders across the lifespan.

### **Participants**

This project consisted of inviting seven primary care providers consisting of three MDs and four NPs to participate in the project. There were no other eligibility requirements. The MDs and NPs taking part in this QI project all were primary care providers, with extra knowledge in geriatric care management, women's health, preventative medicine, chronic disease management and prevention, and men's health. The three MDs were all family medicine physicians and the four NP's were all family nurse practitioners and all prescribe Cologuard to their patient populations due to serving patients ages 50 to 75 years and older.

### **Data Collection**

To ensure participants did not feel coerced or pressured, an email (see Appendix D) was sent to all providers by the Gila Valley Clinic president with a full disclosure form (see Appendix B) letting them know if they did not wish to participate, they may disregard the email. All data and results of the study were stored in a privately protected Excel spreadsheet, which could only be accessed with the use of a password. This information did not contain any participant identifiers throughout the project and was only accessed by the project investigator and the committee members of the QI project. Qualtrics, a web-based survey tool that helps build surveys and collect data, was used for the electronic data collection (Qualtrics, 2019). Links for the pre-survey, brochure, and post-survey were embedded in the email (see Appendix D). Willing and eligible participants completed an anonymous short multiple-choice pre-survey, which was created by the project investigator and approved by her committee (Appendix E). The pre-survey should have taken about 10 minutes to complete and consisted of 15 questions that gave multiple-choice options to choose from as well as an “other” category to fill in for choices not available. The only demographic questions asked were “What type of provider are you?” and “How long have you been prescribing Cologuard?” Participants were then instructed to read the Cologuard information brochure (Appendix F) created by the project investigator, which included national recommended guidelines stated by the USPSTF. The brochure should have taken about five to 10 minutes to read before completing the post-survey. After reading the brochure, participants completed an anonymous short multiple-choice post-survey created by the project investigator following the reading of the information brochure (Appendix G). The post-survey should take about 10 minutes to complete and consisted of 13 questions that gave

multiple-choice options to choose from and two open-ended questions asking if the material was useful and clear and if any improvements could be made for the future. The pre and post-surveys asked the same questions, minus the demographic questions in the post-survey to help determine if knowledge was gained through the information brochure.

### **Data Analysis**

The use of descriptive analysis was used to summarize the quantitative data gained from the intervention. All the information was exported from Qualtrics to an Excel spread sheet by the project investigator and categorized by question number. Subcategories were created for the answers provided on the pre and post-surveys, and answers were compared. The purpose of descriptive statistical analysis helps describe the population being targeted and what was observed (White & Zaccagnini, 2017). Measures of central tendency were used to compare the pre and post multiple-choice survey responses. Bar graphs were used to display range of responses.

## **RESULTS**

### **Description of the Sample Population**

The pre-survey, information brochure, and post-survey were distributed via email to three MDs and four NPs at Gila Valley Clinic in Safford, Arizona. A total of four (57.14%) providers participated. Two (28.57%) MDs completed both the pre-survey and the post-survey. One of these MDs who took the post-survey twice reporting they did not look at the brochure the first time. The second MD who participated in both surveys reported not reading the brochure before answering the post-survey. Two additional participants, one MD and one NP, took the pre-survey but did not respond to the post-survey.

### Survey Responses

The pre-survey and post-survey questions and response options were identical in nature to assess provider knowledge pre-intervention and post-intervention with the use of the Cologuard information brochure. The only differences in the pre-survey were the first two questions identified demographics of the providers in the pre-survey, while the post-survey's last two questions were open-ended to identify if the information was clear, useful, and whether or not changes needed to be made. In the pre-survey, two MDs answered that they have been prescribing Cologuard for one to two years, one MD has been prescribing Cologuard for two to three years, and one NP has been prescribing Cologuard for four or more years.

When asked on the pre-survey, "What age is Cologuard prescribed to individuals?" two (50%) participants stated the correct answer "50-75 years old," and two (50%) participants stated the incorrect answer "50-65 years old." After reviewing the educational information or retaking the post-survey without the use of the brochure, two (100%) participants stated the correct answer "50-75 years old" was the age Cologuard is prescribed to individuals.

When asked in the pre-survey, "What patient is appropriate to receive Cologuard?" three (75%) participants stated the correct answer, "patient with no family/personal history of colorectal cancer or polyps and a patient who had a positive Cologuard five years ago and a negative colonoscopy exam five years ago: A and D," and one (25%) participant stated the incorrect answer, "patient with no family/personal history of colorectal cancer or polyps."

On post-survey, the one (50%) participant who had put the incorrect answer, "patient with no family/personal history of colorectal cancer or polyps" in their pre-survey changed their response to the correct answer, "patient with no family/personal history of colorectal cancer or

polyps and a patient who had a positive Cologuard five years ago and a negative colonoscopy exam five years ago: A and D” post-survey.

In the pre-survey, four (100%) participants answered the question, “What does a negative Cologuard mean?” correctly selecting “the test did not detect abnormal DNA and/or blood in the stool,” but in the post-survey one (50%) participant changed their response to the incorrect answer “all of the above.”

The question asking, “What makes a patient ineligible to provide a Cologuard specimen?” on pre-survey three (75%) participants stated incorrectly, “rectal bleeding” and one (25%) participant stated incorrectly “diarrhea, rectal bleeding, and menstrual and/or vaginal bleeding: A, B, and C.” On post-survey, two (100%) participants changed their responses to the correct answer “all of the above.” The participant who took the post-survey twice initially answered the following question incorrectly as “A, B, and C,” but changed their response to the correct answer, “all of the above” after reviewing the educational brochure.

The participant who answered the post-survey twice initially had a post-test score of 77%, but once they reviewed the information brochure and retook the post-survey, they raised their score to a 92% (Table 2). The results of the pre-survey showed that all four (100%) participants answered incorrectly “yes” to the question, “Do you think many insurances will cover a diagnostic colonoscopy following a positive Cologuard?” and the two (100%) participants who took the post-survey also answered incorrectly “yes”. This was the incorrect response, as the answer should have been “sometimes.”

In the pre-survey, all four (100%) participants answered the question, “What symptoms make a patient ineligible to provide a Cologuard specimen?” incorrectly; however, on post-survey the two (100%) participants answered correctly.

Lastly, the question asking, “How accurate do you think Cologuard is?” three (75%) participants stated correctly “92.3%” and one participant stated incorrectly “88.9%.” On post-test, two (100%) participants stated “92.3%” and the participant who stated “88.9%” did not participate in the post-survey. When asked, “Was the information provided in the educational brochure clear and useful? Explain.” One (50%) participant stated, “What brochure?” and the participant who took the post-survey twice stated, “I didn’t have access to the brochure and Yes but didn’t answer all the questions in the quiz.” When asked, “Are there any changes or improvements you suggest for improving the informational material?” one (50%) participant responded:

*“I found the brochure so am submitting this again, as I filled it out the first time without seeing it. The quiz is confusing because IBD in the brochure means INFLAMMATORY BOWEL DISEASE not irritable bowel disease, and that question puts family history in all the categories, whereas the recommendation and the brochure only put family history of colon cancer, polyps etc as risk factor but not family history of the other conditions.”*

### **Scores on Pre-Survey and Post-Survey**

The scoring was based off scoring 13 out of the 15 questions on both the pre-survey and the post-survey due to the first two questions on the pre-survey asking about demographics and the last two of the post-survey were open-ended questions. Three participants scored a 77% on the pre-survey and one participant scored a 69% on the pre-survey (Table 2). Only two participants responded to the post-survey with a high score of 92% and a low score of 85% (Table 2). The participant who responded to the post-survey twice, initially had a post-survey

score of 77%. Although this project stated the use of measures of central tendency would be used to display the data between the pre-survey and post-survey results, median and mode did not provide statistical data that was useful for this project and the outcome. For pre-survey and post-survey results see Appendix H. Reference Figure 1 for pre-survey and post-survey knowledge comparison. Data for Figure 1 post-survey responses was based on the two providers who took the survey. The first post-survey from the participant who answered the survey twice was omitted from the graph.

TABLE 2. *Descriptive statistics of pre-survey and post-survey*

Measures of Central Tendency	Pre-Survey (%)	Post-Survey (%)
Mean	75%	84.62%
Median	76.92%	84.62%
Mode	76.92%	No Mode

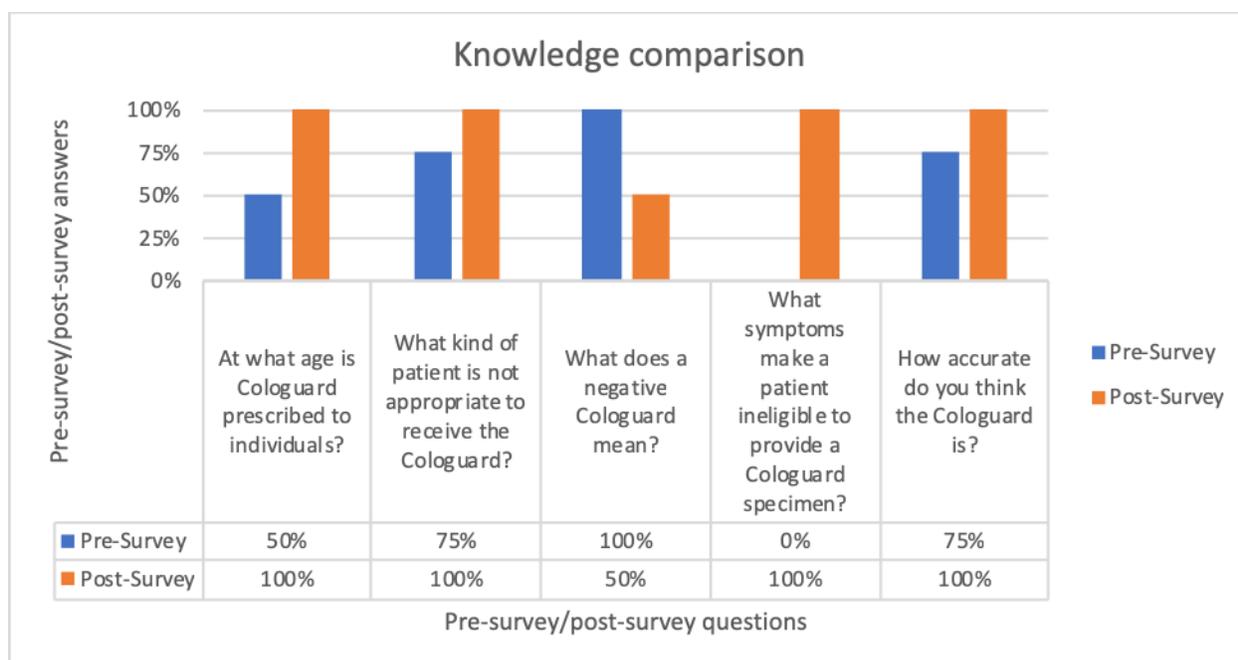


FIGURE 1. Knowledge comparison.

### **Findings Related to Quality Improvement Project Question**

This DNP project focused on educating providers on the recommended use of Cologuard screening for patients who qualify as average-risk individuals and then assessing provider knowledge for the recommended guidelines. According to the results, knowledge of primary care providers improved from an average score of 77% on pre-survey to a high score of 92% on post-survey. The results show that although providers had knowledge previous to the educational intervention regarding Cologuard use, there was still a lack of knowledge among them regarding the nationally recommended guidelines and how and when to prescribe or not to prescribe Cologuard.

## **DISCUSSION**

### **Theoretical Framework Integration**

Primary care providers play a critical role in educating their patients on recommended screening exams and maintenance of health to prevent comorbidities and increase quality of life. Primary care providers are the first line of defense when it comes to informing their patients of when they should start screening exams and when and how these screening exams should be initiated. The OMRU is a theoretical approach that is supported by EBP research, expert opinions, and the use of theory to transfer knowledge into practice (Logan & Graham, 2011). These elements include the ability to adapt and adopt the change, to assess the project, to change attitudes, to increase awareness, to decrease barriers to project implementation, to address concerns in a culturally and socially acceptable manner, to consider economic outcomes, and to evaluate the outcomes (Logan & Graham, 2011). The OMRU was the right theoretical model to use for this QI project; however, more aspects of the model could have been incorporated. The

project investigator provided the participants of the project with evidence-based material to help increase awareness and to potentially help them be more knowledgeable about the nationally recommended guidelines regarding Cologuard use. To fully incorporate the OMRU, the project investigator could have initiated the project face-to-face with the providers to help decrease barriers to project implementation, to help increase knowledge further, and to help the providers decide whether or not to adapt and/or adopt their practice when prescribing Cologuard.

### **Strengths and Limitations**

#### **Strengths**

One strength of this DNP project was the use of a pre-survey, followed by an evidence-based information brochure and post-survey. According to Polit and Beck (2017) the use of a pretest-posttest design can help measure intervention effectiveness quickly. Another strength of this DNP project was it targeted primary care providers in a rural location in Safford, Arizona, who may not receive regular educational interventions such as this one or regular visits from Cologuard representatives.

#### **Limitations**

There were many limitations to this DNP project, which altered the conclusions of this project. First, sending the pre-survey, information brochure, and post-survey via email may have limited how fast providers responded as well as decreased response rate. Another limitation was by using email some providers could not find the information brochure and two providers were not fully aware there was a post-survey to respond to. A total of seven primary care providers were invited to participate in the entire project; however, only four (57.14%) primary care providers participated in the pre-survey and only two (28.57%) providers responded to the post-

survey. Due to time constraint, email reminders to respond to the pre-survey and post-survey could not be resent after being sent the first time. If this were possible, response rates may have increased. Lastly, the question asking, “Do you think many insurances will cover a diagnostic colonoscopy following a positive Cologuard?” was not answered within the educational brochure, making the response for this question difficult to answer, and therefore, that question’s answer was not a valid measure of effectiveness of the project’s educational intervention.

### **Dissemination and Future Implications for Practice**

The results of this DNP project will be sent to the Gila Valley Clinic president via email in December 2019 to help her disseminate the results to the other six primary care providers who were participants in this study. One recommendation is that they reassess current practice with actual recommendations provided by the USPSTF to help guide future practice in prescribing Cologuard. If project investigator adds all the information within the information brochure to help answer all the post-survey questions, this may help increase provider knowledge in this area. Recommendations for the future would be to replicate the QI project with the other eligible participants, to initiate the information through face-to-face contact to increase response rate, or to revise the instructions on how to complete each step of the data collection process. The ultimate future goal for this project is to increase prescribing knowledge for primary care providers regarding Cologuard use. Screening individuals for CRC is important; however, screening exams need to be utilized within the appropriate patient populations.

### **Conclusion**

Screening exams are used to decrease morbidity and mortality within patient populations, which in turn decrease the amount of money being spent for healthcare expenses. It is important

however to realize not all screening exams are appropriate for all risk levels. Some screening exams are meant for low-risk individuals, whereas high-risk individuals typically require more invasive screening modalities

## **OTHER INFORMATION**

### **Resources and Budget**

Resources of this project were nominal, as all information was sent electronically through email. There was no cost to implement this intervention since the pre-survey, brochure, post-survey, and disclosure form were sent via email.

APPENDIX A:  
THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL  
LETTER



Human Subjects  
Protection Program

1618 E. Helen St.  
P.O. Box 245137  
Tucson, AZ 85724-5137  
Tel: (520) 626-6721  
<http://hspp.arizona.edu/compliance/home>

**Date:** October 08, 2019  
**Principal Investigator:** Alexandra Elizabeth More  


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**Protocol Number:** 1910031902  
**Protocol Title:** Educating Primary Care Providers on the Recommended Use of Cologuard  


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**Determination:** Human Subjects Review not Required  


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**Documents Reviewed Concurrently:**  
**HSPF Forms/Correspondence:** *determination\_y2019-08-15.pdf*  
**Other Approvals and Authorizations:** *COI Certification Complete for 1910031902.msg*

**Regulatory Determinations/Comments:**

- Not Human Subjects Research as defined by 45 CFR 46.102(e): as presented, the activities described above do not meet the definition of research involving human subjects as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. "

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

**APPENDIX B:**  
**DETERMINATION OF HUMAN RESEARCH: DISCLOSURE FORM**

## **Educating Primary Care Providers on the Recommended Use of Cologuard**

**Alexandra More, RN, BSN**

The purpose of this project is to educate primary care providers at Gila Valley Clinic in Safford, Arizona on the recommended use of Cologuard screening for patients who qualify as average-risk individuals and then assessing provider knowledge for the recommended guidelines for Cologuard.

If you choose to take part in this project, you will be asked to take a 15-question pre-survey, read an informational brochure prepared by the project investigator and take a 15-question post-survey. It will take approximately 20 minutes to complete both surveys and read the brochure. There are no foreseeable risks associated with participating in this project and you will receive no immediate benefit from your participation. Survey responses are anonymous.

If you choose to participate in the project, participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw at any time from the project. In addition, you may skip any question that you choose not to answer. By participating, you do not give up any personal legal rights you may have as a participant in this project.

For questions, concerns, or complaints about the project, you may call Alexandra E. More, RN, BSN at 520-437-7783 or [aemore@email.arizona.edu](mailto:aemore@email.arizona.edu).

APPENDIX C:  
SITE APPROVAL LETTER

Gila Valley Clinic  
1680 S 20<sup>th</sup> Avenue  
Safford, AZ 85546

September 16, 2019

University of Arizona Institutional Review Board  
c/o Office of Human Subjects  
1618 E Helen St  
Tucson, AZ 85721

Please note that Ms. Alexandra More, UA Graduate Student, has permission of the Gila Valley Clinic to conduct a quality improvement project at our Safford, AZ facility for her study, "Educating Primary Care Providers on the Recommended Use of Cologuard."

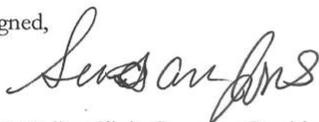
Ms. More will contact employees via email through the president of the Gila Valley Clinic. One email will be sent to the site President and then distributed to all the providers. The providers will be asked to read the disclosure form and take a 15-question pre-survey, read an informational brochure prepared by the student and take a 15-question post-survey. It will take approximately 20 minutes to complete both surveys and read the brochure. There are no foreseeable risks associated with participating in this project and we will receive no immediate benefit from participation. Survey responses are anonymous.

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits. We may withdraw at any time from the project. In addition, we may skip any question that we choose not to answer. By participating, we do not give up any personal legal rights we may have as a participant in this project. Her plan is to have the email distributed by the end of September 2019. Ms. More's quality improvement project activities will be completed by December 10, 2019.

Employees will not be allowed time from their work duties to complete the surveys. Ms. More also has agreed to provide to my office a copy of the University of Arizona IRB-approved, stamped consent document before sending the project email, and will also provide a copy of any aggregate results.

If there are any questions, please contact my office.

Signed,



Gila Valley Clinic Company President

APPENDIX D:  
COLOGUARD QUALITY IMPROVEMENT EMAIL

## Recruitment Email

Hello, my name is Alexandra More and I am a family nurse practitioner student at the University of Arizona and I am asking for your participation in my quality improvement educational intervention regarding Cologuard. Please read the disclosure form first. If you choose to participate, first please take the pre-survey. Next, look over the Cologuard brochure. Lastly, respond to the post-survey. Your participation should take no more than 20 minutes of your time to complete. Your help with this quality improvement project is greatly appreciated. I look forward to reviewing your responses.

### Pre-Survey

Link: [https://uarizona.co1.qualtrics.com/jfe/form/SV\\_3F8GcmjYvpOJsBn](https://uarizona.co1.qualtrics.com/jfe/form/SV_3F8GcmjYvpOJsBn)

### Post-Survey

Link: [https://uarizona.co1.qualtrics.com/jfe/form/SV\\_bImSLYWZDi5WpRr](https://uarizona.co1.qualtrics.com/jfe/form/SV_bImSLYWZDi5WpRr)

## 2 Attachments



APPENDIX E:  
COLOGUARD PRE-QUESTIONNAIRE

## Cologuard Pre-Questionnaire

This short-multiple choice questionnaire will help the project investigator determine knowledge regarding Cologuard pre-education intervention. The questions are based off your knowledge regarding Cologuard prescribing. All surveys will be kept anonymous. By answering these questions, you have agreed to let me use this information for the quality improvement project. Thank you for completing the questionnaire.

- 1) What type of provider are you?
  - MD
  - NP
  - Other
  
- 2) How long have you been prescribing Cologuard?
  - 0-1 years
  - 1-2 years
  - 2-3 years
  - 3-4 years
  - 4 or more years
  - Other
  
- 3) At what age is Cologuard prescribed to individuals?
  - 20-30 years old
  - 30-45 years old
  - 50-65 years old
  - 50-75 years old
  - 65-80 years old
  
- 4) What kind of patient is not appropriate to receive the Cologuard?
  - Family/personal history of irritable bowel disease
  - Family/personal history of polyps
  - Family/personal history of colorectal cancer
  - Family/personal history of Lynch Syndrome and/or Familial Polyposis
  - Family/personal history of Crohn's Disease and/or Ulcerative Colitis
  - None of the above
  - All of the above
  
- 5) What patient is appropriate to receive the Cologuard?
  - Patient with no family/personal history of colorectal cancer or polyps
  - Patient with Lynch Syndrome
  - Patient with diarrhea
  - Patient who had a positive Cologuard 5 years ago and a negative colonoscopy exam 5 years ago.
  - A and D

- 6) How often is the Cologuard recommended for colorectal cancer screening by the United States Preventative Task Services?
- Every 10 years
  - Every 5 years
  - Every 1 to 3 years
  - Every year
- 7) What happens if the Cologuard comes back with a positive result?
- Have another Cologuard in 3 months
  - Have a diagnostic colonoscopy
  - Have another Cologuard in 3 years
  - Do not do anything
- 8) How often is Cologuard covered by Medicare?
- Every 3 years
  - Every year
  - Every 6 months
  - Every 5 years
  - Every 10 years
- 9) What does a negative Cologuard mean?
- The patient does not have polyps or colorectal cancer
  - The patient does not need another colorectal cancer screening
  - The test did not detect abnormal DNA and/or blood in the stool
  - None of the above
  - All of the above
- 10) What symptoms make a patient ineligible to provide a Cologuard specimen?
- Diarrhea
  - Rectal bleeding
  - Menstrual and/or vaginal bleeding
  - Cuts or wounds on the hands that are bleeding
  - A, B, and C
  - All of the above
  - None of the above
- 11) Do you think many insurances will cover a diagnostic colonoscopy following a positive Cologuard?
- Yes
  - No
  - Sometimes
- 12) How accurate do you think the Cologuard is?
- 100%
  - 34.4%
  - 92.3%

- 58.7%
- 88.9%

13) Before prescribing Cologuard, do you obtain an extensive personal and family history regarding colorectal health?

- Yes
- No
- Sometimes

14) If a patient comes in with rectal bleeding that is bright red in color and wants to be screened using the Cologuard test, would you prescribe them this test (patient has no personal or family history and had a negative colonoscopy 5 years ago)?

- Yes
- No
- Sometimes

15) Should a patient have a Cologuard test if they are having abdominal pain and a change in bowel habits?

- Yes
- No
- Sometimes

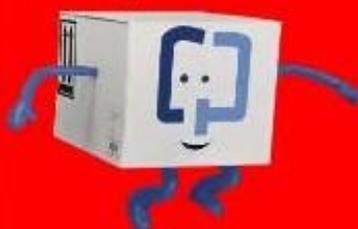
APPENDIX F:  
COLOGUARD BROCHURE

*Cologuard demonstrates a 92.3% colorectal cancer sensitivity and a 96.6% colorectal cancer specificity.*



**WARNING:**  
*The rate of false positives increases with age!*

*The choice to screen individuals over the age of 75 year old should be made on an individual basis in consultation with a healthcare provider.*



References:  
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028011.pdf?e=52444953993  
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**cologuard**  
Rx only

*Screen average risk patients ages 50 years and older every 3 years with Cologuard*



## Patient Education

*Patients should not provide a sample if:*

- They have diarrhea.
- If blood is in their urine or stool.
- If they are menstruating.
- If they have cuts or wounds on their hands
- If they have bleeding hemorrhoids.
- If they have rectal bleeding.

*To ensure integrity:*

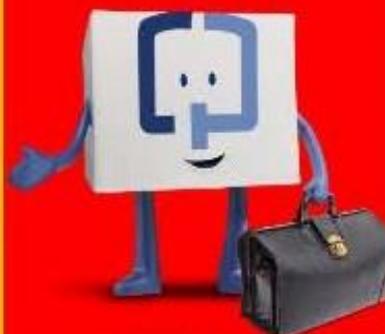
- Sample must be received by the laboratory within 72 hours following collection.

*Cologuard May:*

- Produce false negatives or false positives

*A positive Cologuard does not mean colorectal cancer.*

*Cologuard detects hemoglobin and DNA markers for colorectal cancer, cancerous polyps, and precancerous polyps.*



*A negative Cologuard does not guarantee absence of cancer or advanced adenomas*

## Contraindications

- Personal or family history of colorectal cancer, adenomas, or other related cancers.
- Inflammatory Bowel Disease
- Chronic Ulcerative Colitis
- Chron's Disease
- Familial Adenomatous Polyposis
- Hereditary Non-Polyposis Colorectal Cancer Syndrome or Lynch Syndrome
- Peutz-Jegher's Syndrome
- MYH-Associated Polyposis
- Gardner's Syndrome
- Turcot's or Crail's Syndrome
- Cowden's Syndrome
- Juvenile Polyposis
- Cronkhite-Canada Syndrome
- Neurofibromatosis
- Familial Hyperplastic Polyposis

APPENDIX G:  
COLOGUARD POST-QUESTIONNAIRE

## Cologuard Post-Questionnaire

This short-multiple choice questionnaire will help the project investigator determine knowledge regarding Cologuard post-education intervention. The questions are based off your knowledge regarding Cologuard prescribing. All surveys will be kept anonymous. By answering these questions, you have agreed to let me use this information for the quality improvement project. Thank you for completing the questionnaire.

- 1) At what age is Cologuard prescribed to individuals?
  - 20-30 years old
  - 30-45 years old
  - 50-65 years old
  - 50-75 years old
  - 65-80 years old
  
- 2) What kind of patient is not appropriate to receive the Cologuard?
  - Family/personal history of irritable bowel disease
  - Family/personal history of polyps
  - Family/personal history of colorectal cancer
  - Family/personal history of Lynch Syndrome and/or Familial Polyposis
  - Family/personal history of Crohn's Disease and/or Ulcerative Colitis
  - None of the above
  - All of the above
  
- 3) What patient is appropriate to receive the Cologuard?
  - Patient with no family/personal history of colorectal cancer or polyps
  - Patient with Lynch Syndrome
  - Patient with diarrhea
  - Patient who had a positive Cologuard 5 years ago and a negative colonoscopy exam 5 years ago.
  - A and D
  
- 4) How often is the Cologuard recommended for colorectal cancer screening by the United States Preventative Task Services?
  - Every 10 years
  - Every 5 years
  - Every 1 to 3 years
  - Every year
  
- 5) What happens if the Cologuard comes back with a positive result?
  - Have another Cologuard in 3 months
  - Have a diagnostic colonoscopy
  - Have another Cologuard in 3 years
  - Do not do anything
  - Other

- 6) How often is Cologuard covered by Medicare?
- Every 3 years
  - Every year
  - Every 6 months
  - Every 5 years
  - Every 10 years
- 7) What does a negative Cologuard mean?
- The patient does not have polyps or colorectal cancer
  - The patient does not need another colorectal cancer screening
  - The test did not detect abnormal DNA and/or blood in the stool
  - None of the above
  - All of the above
- 8) What symptoms make a patient ineligible to provide a Cologuard specimen?
- Diarrhea
  - Rectal bleeding
  - Menstrual and/or vaginal bleeding
  - Cuts or wounds on the hands that are bleeding
  - A, B, and C
  - All of the above
  - None of the above
- 9) Do you think many insurances will cover a diagnostic colonoscopy following a positive Cologuard?
- Yes
  - No
  - Sometimes
- 10) How accurate do you think the Cologuard is?
- 100%
  - 34.4%
  - 92.3%
  - 58.7%
  - 88.9%
- 11) Before prescribing Cologuard, do you obtain an extensive personal and family history regarding colorectal health?
- Yes
  - No
  - Sometimes

12) If a patient comes in with rectal bleeding that is bright red in color and wants to be screened using the Cologuard test, would you prescribe them this test (patient has no personal or family history and had a negative colonoscopy 5 years)?

- Yes
- No
- Sometimes

13) Should a patient have a Cologuard test if they are having abdominal pain and a change in bowel habits?

- Yes
- No
- Sometimes

14) Was the information provided in the educational brochure clear and useful? Explain.

15) Are there any changes or improvements you suggest for improving the informational material?

APPENDIX H:  
PRE-SURVEY AND POST SURVEY RESULTS

Participant	Pre-Survey				Post-Survey		
	1	2	3	4	1	1	2
Question 1	MD	MD	NP	MD	50-75 years old	50-75 years old	50-75 years old
Question 2	2-3 years	1-2 years	4 or more years	1-2 year	All of the above	All of the above	All of the above
Question 3	50-75 years old	50-65 years old	50-65 years old	50-75 years old	Patient with no family/personal history of colorectal cancer or polyps	A and D	A and D
Question 4	Family/personal history of colorectal cancer	All of the above	All of the above	All of the above	Every 1 to 3 years	Every 1 to 3 years	Every 1 to 3 years
Question 5	A and D	A and D	Patient with no family/personal history of colorectal cancer or polyps	A and D	Have a diagnostic colonoscopy	Have a diagnostic colonoscopy	Have a diagnostic colonoscopy
Question 6	Every 1 to 3 years	Every 1 to 3 years	Every 1 to 3 years	Every 1 to 3 years	Every 3 years	Every 3 years	Every 3 years
Question 7	Have a diagnostic colonoscopy	Have a diagnostic colonoscopy	Have a diagnostic colonoscopy	Have a diagnostic colonoscopy	The test did not detect abnormal DNA and/or blood in stool	The test did not detect abnormal DNA and/or blood in stool	All of the above
Question 8	Every 3 years	Every 3 years	Every 3 years	Every 3 years	A, B, and C	All of the above	All of the above
Question 9	The test did not detect abnormal DNA and/or blood in stool	The test did not detect abnormal DNA and/or blood in stool	The test did not detect abnormal DNA and/or blood in stool	The test did not detect abnormal DNA and/or blood in stool	Yes	Yes	Yes
Question 10	A, B, and C	Rectal Bleeding	Rectal Bleeding	Rectal Bleeding	92.3%	92.3%	92.3%
Question 11	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Question 12	92.3%	92.3%	92.3%	88.9%	No	No	No
Question 13	Yes	Yes	Yes	Yes	No	No	No
Question 14	No	No	No	No	I didn't have access to the brochure.		What brochure?

Participant	Pre-Survey				Post-Survey		
	1	2	3	4	1	1	2
Question 15	No	No	No	No	I found the brochure so am submitting this again, as I filled it out the first time without seeing it. the quiz is confusing because IBD in the brochure means INFLAMMOTORY BOWEL DISEASE not irritable bowel disease, and that question puts family hx in all the categories, whereas the recommendation and the brochure only put family hx of colon cancer, polyps etc as risk factor but not fam hx of the other conditions.		

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