IMPLEMENTATION OF AN EVIDENCE-BASED TOOLKIT TO IMPROVE COLORECTAL CANCER SCREENING IN A FEDERALLY QUALIFIED HEALTH CENTER

A Scholarly Project

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree of

Doctor of Nursing Practice

By

Stephanie B McKithan

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Lynchburg, VA

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Scholarly Project Chair Approval:

Sherri Walker, Ph.D., PMHNP-BC Date

ABSTRACT

The change in payor fee-for-service to value-based care is creating an opportunity for primary care clinics nationally to adjust their focus to meeting key clinical quality measures during patient encounters. Colorectal screening is one of such quality measures. Previous research has shown that early detection saves lives. The guidelines have lowered the recommended age of initial screening to 45 due to the incidence of colorectal cancer in younger patients. But with all the objectives that need to be met in the limited time of the visit, how can nurse practitioners improve their efficiency? This evidence-based project assessed the implementation of eleven interventions combined into a toolkit designed to increase the clinic's compliance to federally qualified health center (FQHC) standards of care by increasing colorectal cancer screening in the primary care setting. These steps were aimed at identifying patients eligible for screening along with predisposing high-risk factors, arming them with education to understand the importance of screening and the various methods, and priming a shared decision-making conversation with the nurse practitioner on arrival to the exam room. An eight-week trial of the toolkit revealed a significant increase in screening participation of the pilot clinic over the cohort clinic. Additionally, there was an overall increase in a secondary measure of improving staff's knowledge of colorectal cancer and a third measure of bringing screening rates up to North Carolina benchmarks. A multi-interventional toolkit can improve essential screening and early detection of colorectal cancer, thus meeting clinic goals and standards of care and ultimately improving patient outcomes in the form of quality and subsequent length of life.

Keywords: Colorectal cancer, screening, value-based care, interventions, primary care.

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SECTION ONE: INTRODUCTION

Colorectal cancer (CRC) is the second cause of cancer-related death, affecting both men and women in the United States. It accounted for 51,869 deaths in 2020 (CDC, 2023). Incidence ranges from 29-35 per 100,000, and mortality from CRC is 12-14 per 100,000 (ACS, 2022). For every 100,000 people, 33 were diagnosed with colorectal cancer, and 13 died. In North Carolina, where this project will be implemented, only 71% of the population over 50 have had screening, and the percentage is lower in the 45-49-year-old range, which was recently added to recommendations due to the growing rate of advanced cancer in this demographic. Colorectal cancer is not usually deadly when localized and caught before it can metastasize to other body regions (ACS, 2023). Studies have shown that preventive screening can identify and remove benign cancerous precursors, preventing invasive cancer. Screening allows early detection of cancer sooner than symptoms would have arisen, alerting the patient to a problem before a later stage of progression (Helsingen & Kalager, 2022). Data shows a 91 percent chance of survival when a colon lesion is localized, but when it has spread to a distant organ, the survival rate drops to 14 percent (ACS, 2023). Colorectal cancer screening (CRCS) is the best way to identify a malignant mass before it has a chance to metastasize.

Background

Screening can identify CRC early when survival rates are highest (ACS, 2023). CRC begins from a small precancerous growth called a polyp. CRCS is designed to either visualize and remove polyps before they turn cancerous, detect blood in the stool that may be caused by a cancerous growth, identify altered DNA in the stool, image the colon to look for abnormal findings along the colon walls, or a combination of these methods. Despite CRC being a disease

mainly affecting older adults, its occurrence in younger people is increasing. Of the estimated 153,020 new cases of CRC estimated for 2023, 13%, or 19,550, will be in people younger than 50 (Siegel et al., 2023). Because of the increase in the incidence of colon cancer in increasingly younger patients, the American Cancer Society changed its recommendations to begin screening at age 45 in 2018. In 2021, the American College of Gastroenterology also changed its recommendations to include this younger population (USPSTF, 2021). Those with a family history of colon cancer should be screened even earlier.

There are disparities among patients concerning CRC screening, diagnosis, and mortality. Most of the disparities have a direct link to socioeconomic differences among Americans. One report found that patients with lower socioeconomic statuses were 40% more likely to develop CRC than those with higher statuses, primarily due to risk factors like smoking, obesity, and poor screening uptake (Siegel et al., 2023). The organization where the project will take place is funded partially through the US Department of Agriculture because of the rural locations and farm workers that are cared for there. Rural community health organizations such as this FQHC must be equipped to address disparities and improve equity among the poorer rural Americans that they serve.

Colonoscopy-alternative, noninvasive methods for screening exist. These include the Fecal Immunochemical Testing (FIT), which in most cases has replaced the fecal occult blood (FOBT) test because it does not require dietary or medication restrictions, needs only one sample instead of three, and can differentiate blood from the lower gastrointestinal (GI) tract (Burke et al., 2022). Another alternative home test is Cologuard, a stool DNA test that detects blood traces and abnormal cancer DNA markers. One less common noninvasive screening is CT colonography, which takes images of the colon and rectum but is usually reserved for those who

cannot have a colonoscopy. There is a relatively new blood test called Septin-9, which is being studied for its accuracy in sensitivity and specificity. It is not yet recommended by any of the national organizations but may be eventually.

The three forms of invasive screenings are colonoscopy, flexible sigmoidoscopy (FS), and capsule colonoscopy (Burke et al., 2022). Colonoscopy, as mentioned before, is considered the gold standard for screening. Once a polyp or lesion is identified, it can be removed and biopsied under a diagnostic and therapeutic colonoscopy. Flexible sigmoidoscopy can also identify and remove polyps, but only in the descending colon, sigmoid, and rectum. Capsule colonoscopy visualizes the entire colon but with less accuracy than colonoscopy and without removal. Patients with positive non-invasive screens need to have a follow-up with a high-quality diagnostic colonoscopy. Patients with either non-invasive or invasive negative screens need to continue scheduled follow-ups according to the recommended guidelines.

The recommended frequency of each screening type differs. Colonoscopy can be performed every ten years in the presence of no abnormal findings. Colonography is recommended every five years, flexible sigmoidoscopy every five to ten, capsule colonoscopy every five, Cologuard every three, and FIT or FOBT every year (Burke et al., 2022). Either form of screening can serve as a baseline for patients with low to average risk. Still, patients who have a personal or family history of a hereditary syndrome such as Lynch, adenomatous polyposis, serrated polyposis, Hamartomatous polyposis, a personal history of inflammatory bowel disease, a serrated polyp, or advanced adenoma need to have colonoscopy screening as a baseline and intermittently due to the increased risk of CRC (Burke et al., 2022).

Documentation of appropriate patient screening is necessary for all organizations but is of particular interest to healthcare centers that receive federal funding, FQHCs. The Health

Resources Services Administration (HRSA) and Uniform Data Set (UDS) are used to assess the performance of FQHCs. Funding requires that the organization meets various quality measures and benchmarks outlined by the Centers for Medicare and Medicaid. The higher the level of reporting of these measures, the greater the measure of quality of the organization. Currently there are merit-based incentive payments for meeting these quality measures. Healthcare is currently paid based on a fee-for-service model, but this is soon to be replaced by a value-based model, which, it is believed, will decrease healthcare costs, and improve the quality of care. Reporting basic preventive services such as CRCS is one of the incentivized quality measures, but eventually, failure will be penalized. Proactive health organizations are attempting to meet these measures to gain incentives and allow staff time to acclimate to this new form of reporting while failure does not result in loss of resources.

The American Cancer Society has long provided grants to focus attention on cancer prevention. They present a list of focuses organizations may choose from and then award money to meet these initiatives. The FQHC this quality improvement project will be performed with has chosen CRCS as its target for 2023. The clinic's average baseline screening rate was 8.7 percent at the beginning of 2023. The goal of the ACS and the FQHC for 2023 was to improve the current baseline rate by ten percentage points before December 31.

The usual practice for colorectal cancer screening at the FQHC is to give all patients the opportunity to have a colonoscopy, FIT, or Cologuard test. Only the FIT has been without cost to sliding fee patients. Staff is instructed to call to remind patients of the test after two weeks have passed, but they have had difficulty closing the loop. Busy nurse practitioners aim to screen all eligible patients and document this in the EHR once resulted. Still, inconsistent reporting was found during a recent chart audit, noting room for improvement both in the EHR platform and

with documentation practices which could lead to improved identification of patients who are not up to date.

In addition to the grant, the standard of care is that all patients, regardless of insurance status, may receive a FIT home stool test from the clinic. Additionally, this year, eligible patients insured by United Healthcare have been offered Cologuard. The FQHC has also secured Cologuard for all patients with limited resources with a zero fee. There are many services in place to meet the screening goals of the organization this year, yet the rates of screening and reporting remained low at the mid-year mark.

Problem Statement

Primary care clinics need help achieving their screening and reporting goals. COVID-19 caused many preventive health services to come to a halt. Now that the pandemic is no longer a hindrance to screening access, patients and nurse practitioners need to return to pre-pandemic screening guidelines to avoid the morbidity and mortality that accompanies late CRC diagnosis. Clinic staff needs education and tools to assist them in providing every patient with the appropriate screening and documenting its completion in the EHR to satisfy organizational objectives. This is the right time for such an initiative because of the available screening access and the need to return to pre-pandemic preventive care.

Purpose of the Project

This project aims to implement a toolkit to improve the assessment, promotion, and successful documentation of CRCS by providers in the 45–75-year-old population. In 2016, the Community Preventive Services Task Force (CPSTF) stated that improvement in CRCS uptake would require the use of multicomponent interventions (2019). CPSTF continued by reporting that when an intervention to increase community demand was added to another component, there

was a median 4.9 percent increase in CRCS, and when an intervention to increase community access was added to another approach, there was an increase of 17.1 percent (National Colorectal Cancer Roundtable, 2022). The suggestion was to include two or more interventions that either (1) increase demand, such as reminders or one-on-one education; (2) improve access, like reducing out-of-pocket costs and structural barriers; and (3) increase nurse practitioner delivery of the services through activities such as reminders, assessment, feedback, or incentives.

This multi-component toolkit will consist of clinician-focused strategies to enhance patient compliance. They meet each of these categories by providing:

(1) a pre-interventional request for EHR enhancements to streamline the documentation process, decreasing the chances of unscreened patients being mistaken as up-to-date and screened patients not being counted as incomplete. The organization's information technology department will be asked to assist in streamlining the assessment section of the EHR to eliminate CRCS documentation that does not meet reporting analytics requirements.

(2) An educational session for staff outlining the importance of CRCS to the patient and of meeting guidelines for the organization. The project will launch with an office lunch and learn. The effectiveness of education will be measured using a pre and post-test. During this time, all parts of the toolkit will be reviewed (see Appendix M).

(3) The toolkit will include patient CRC education from the American Cancer Society (English) and the Center for Disease Control (Spanish) that will be given to patients aged 45-75 (see Appendix J and Appendix K) and a questionnaire drawn from a validated assessment tool to assess screening status and personal level of risk (see Appendix G). It will provide an explanation of each type of CRCS and allow for patient input of personal preference. This will be utilized when the patient is in the exam room.

(4) This will ultimately lead to a patient-centered shared decision-making conversation, which the nurse practitioner will receive training to do.

(5) There will be guidance for administrative staff in printing out a daily list of patients needing CRCS assessment from the EHR so they can be appropriately targeted with this interdisciplinary effort during the appointment

(6) There will be low or no-cost screening options through grants and allotments from multiple sources.

(7) While the resources are available, a twenty-dollar gas card will be awarded to participants who complete screening. During the encounter, the nurse practitioner can order the screening.

(8) The clinicians will have reminders to call patients two weeks after the encounter to urge them to complete at-home screening and return it or to follow through with the colonoscopy appointment.

(9) A CRCS log (see Appendix I) will be used to keep track of patient statuses for reminders and follow-up.

(10) The nurse practitioner will be given her personal screening rate compared to the organizational goal, which will be updated throughout the project period.

While colonoscopy remains the gold standard for screening, there are options for patients who are hesitant or who refuse the 2-day involvement that a typical colonoscopy requires. This initiative will help patients, with provider guidance, explore all patient-centered, appropriate options.

Clinical Question

The PICOT, or clinical question of this scholarly project is (P) among primary care clinicians and staff, (I) does implementation of a multi-interventional evidence-based toolkit, (C) compared to usual practice, (O) improve colorectal cancer standards of care and screening rates (T) during an 8-week pilot period?

SECTION TWO: LITERATURE REVIEW

The purpose of the literature review was multifold. Educational material for the staff was needed to outline the requirements to meet the patient screening objective and documentation requirements. Tools to assess the patient's current screening status were needed. Patient-centered education without medical jargon was needed for handouts. To compile all of this, a literature search for the most recent information was undertaken.

Search Strategy

CINAHL, EBSCO, and Google Scholar were searched using the terms colorectal cancer screening paired with screening guidelines, shared decision-making, merit-based incentive payment system (MIPS), Centers for Medicare & Medicaid Services (CMS), accountable care organization (ACO), clinical quality measure (CQM), uniform data system (UDS), increase, improve, enhance, adherence, compliance, intervention, strategies, federally qualified health center, best practice, and staff education. The dates were limited to the last five years, and the English language limit was placed on peer-reviewed, full-text articles only. The return articles from this search were then reduced to include only articles applicable to this project. The Center for Disease Control and Prevention (CDC), the United States Preventive Services Task Force (USPSTF), the American College of Gastroenterology (ACG), the National Colorectal Cancer

Round Table (NCCRT), and the American Cancer Society (ACS) were also searched for applicable material.

Critical Appraisal

The studies that led to the scholarly project were varied and focused on education regarding organizationally accepted guidelines for screening from the USPSTF and evidence-based methods that have proven effective in prior studies to improve the uptake of CRCS. These included staff educational methods and evaluation, the benefits of shared decision-making, implementing practice change, and interventions to improve clinic compliance. The ACS (2022) reported that combined interventions are most effective. Because the toolkit includes multiple interventions, each was individually researched to establish relevancy and validation from previous studies (see Appendix B).

The most convincing evidence for practice change was found in systematic reviews. One such was a review by Woudstra & Surmond (2019). They sought to discover how different narratives could influence a patient's decision to have CRCS. Out of over 1400 articles, 15 were chosen for inclusion in the review. These were qualitative studies, so the results were difficult to extract and categorize as there were many different narratives. From the study, they concluded that addressing perceived barriers, demonstrating the screening procedure, telling the experiences of others, and focusing on outcomes of the screening decision were very effective in patient decisions to screen. The most effective narrative in multiple studies was conveying to the patient that the 'best test is the one that gets done.' Studies have shown that 68% of patients trust their personal provider for cancer screening information over national health organizations and other doctors (ACS, 2022). A strong recommendation from a healthcare provider was noted to be the most influential factor in a patient's decision for preventive care and their screening

behaviors. Patient-centered provider education for this project will recommend including this phrase.

The second systematic review by Davis et al. (2018) was designed to review clinic interventions that increased CRCS in rural and low-income areas. They used 27 studies that met inclusion criteria and found increased uptake of screening that were the most effective interventions were kits by direct mail, use of a pre-addressed stamped package, patient reminders, and in-clinic distribution of tests. This project will also incorporate a convenience aspect with clinic-ordered or distributed tests and referrals and will continue usual care, which uses patient reminders to complete screening two weeks after the kit has been given or ordered, or referral has been made. The CPSTF performed a systematic review of interventions that increased CRCS, and one of the largest increases was found when translation services were provided, resulting in a 62.7 percent increase in screening (2019). This clinic provides translation services routinely and CRCS patient education will be given in Spanish.

Four randomized control trials presented the second-best level of evidence for the project. Sepucha et al. (2023) did a trial to see if shared decision-making would improve CRCS rates. This study employed 800 patients whose CRCS was canceled due to the pandemic. They randomly assigned half to the usual care and half to the shared decision-making intervention. The intervention group received a three-page decision aid and a call from a decision coach. The usual care group received a call to reschedule only. The intervention group was scheduled within 6 months at a rate of 35 percent, versus 23 percent in the control arm. The conclusion was that offering alternatives and incorporating patients' preferences led to higher screening rates. This will be incorporated into the current project as part of the shared decision-making that the nurse practitioner will be trained to have with patients. A study from one community health center

found that in patients offered only colonoscopy compared to stool tests had lower screening adherence and in three-year follow-up; there was still a higher rate of screening in those given a choice (NCCRT, 2022). This toolkit also uses a decision aid, and the nurse practitioner incorporates patient preferences, if possible, during shared decision-making for appropriate CRCS modalities (see Appendix G). This may not generalize in non-pandemic times, and the participants did already agree to CRCS before the pandemic, so there was no convincing that it was necessary, but the intervention did show a significant improvement in returning patients over the usual care, so there is strength in the intervention that may be effective in a fresh population. Hwang et al. (2019) did a study to see if audit and feedback were a beneficial means to improve cancer screening rates. They randomly placed medical residents into one of three arms of the study. All three groups received a list of quality measures. The second group also received their personal rates of screening patients and the target rate for primary care practices. The third group received their personal rate and the average rate of same-year medical students. The second group's rates increased from 65 to 73 percent in the 13-month trial period. This was significant and led to the conclusion that providing individual scores and clinic target goals can significantly improve CRCS rates and composite quality scores.

In line with the audit and feedback method, this project will provide personal and organizational goal rates to the nurse practitioner at the initiation of the pilot and periodically throughout. Though this study used medical residents, the fact that they were not yet practicing did not significantly alter the impact of this intervention. Green et al. (2022) evaluated 4,653 patients who were randomly assigned to usual care or interventions with mailed fecal tests or information on scheduling a colonoscopy plus either telephone assistance, or nurse navigation. The mailed test plus follow-up call yielded 21 percent improved rates of screening. This adds

proof that increased access and convenience will increase uptake of CRCS. By improving access and convenience, this clinic should also be able to increase screening. Coronado et al. (2018) had a random controlled trial to compare methods of reminding patients to complete their mailed CRCS test. All patients with a portal received an email through the portal, but they compared these paired with a reminder letter, automated or live call, or text message. There were 2,772 subjects. They found that the live call yielded the highest rate of return over printed reminders of any form. This large study with diverse sampling showed the value of telephone reminders over any other form of reminder. The usual care for the clinic utilizes phone calls, which will be continued throughout the project using a formal screening log to keep track of and close the loop on all outstanding, unresulted screenings (see Appendix I).

Wilemse et al. (2022) brings this literature appraisal's only quasi-experimental study. They conducted a literature search followed by designing and implementing a multifaceted bundle to improve CRCS in primary care clinics. Their bundle consisted of provider recommendations to screen, in-office FIT kits, patient education of importance, collection instructions given by support staff, pre-addressed postage-paid return kits, and a reminder text one week after and a call two weeks after the visit. Six months after implementation, screening rates increased from 45 to 65 percent among the five primary care clinics in which it was piloted. Plan, do, study, act (PDSA) was performed every three months to improve the program.

Two cohort studies were evaluated in this literature review. These findings, though of a lower level of evidence, also provided adequate support for the project. Mojica et al. (2022) examined different tactics from nine primary care clinics to increase CRCS. They used surveys, observational visits, and informal interviews to draw correlations of the most beneficial activities for increased CRCS uptake. The results were that clinics that utilized MAs to the full scope of

practice by reviewing patient options and providing instructions, clinics that reviewed charts before the visits to assess eligibility, and finally, those that had a protocol for reminding patients to return their tests had rates of screening that were between 33-43% versus 5-15%.

This project will include the aspect of a pre-visit chart review of eligibility, and though MAs are not providing education, the nurse or MA will ensure the form that reviews options along with a video link to testing instructions is given to each patient as well as maintaining the usual care of patient reminders (see Appendix G). Walker et al. (2018) performed a huge study of 59 FQHCs in 7 states to assess the impact of evidence-based activities and clinical correlates on improved CRCS rates. Despite the variety of clinics and staffing ratios in the clinics evaluated, the correlates that most dictated improved CRCS rates were the ease of retrieving CRCS statuses from the EHR and timely feedback from managers. This toolkit will ensure CRC statuses are available during the encounter, and feedback on screening rates will be provided as the dashboard updates, keeping in mind that scores do not immediately reflect performance.

Soriano et al. (2021) designed a validated questionnaire to assess CRC status and risk level. This is important because it can direct the frequency of repeated screening and the appropriate screening methods. This tool incorporated previously validated questions with novel ones and created an electronic format. This study will not use electronic delivery, but permission was obtained to use the tool (see Appendix E), which was partially augmented and printed for the patient status portion of the questionnaire.

Synthesis

The literature to date described many interventions used by outpatient settings to increase screening rates. Some of the most important findings for improved CRCS completion were

discussed in the various articles. Those that are most pertinent to this scholarly project fall into two categories: those that affect patients and those that affect the clinic.

The evidence-based interventions selected for this project include the staff being prepared daily with a list of patients that needed screening (Mojica et al., 2022; Walker et al., 2018) and having ancillary clinic staff initiate education to begin the thought process of screening options (Mojica et al., 2022). In the literature, the MAs did this by discussing options before rooming the patient, but due to staffing limitations, the nurse or MA will accomplish this by ensuring qualified patients have received the written literature discussing options at check-in (see Appendix J and Appendix K) and have completed the questionnaire. Having written explanations of the different screening methods will also ensure all patients get uniform information.

Walker et al. (2018) found evidence that staff's ability to utilize the EHR section that addresses the CRC status easily was effective. During the pilot launch, the researcher will ensure that the staff can pull data from the EHR for the morning list and that the nurse practitioner is documenting the encounter in the correct location and with all the needed elements to satisfy the goal from a searchable dashboard for reports by UDS.

Interventions tied directly to providers included receiving timely feedback (Walker et al., 2018) and arming them with their personal quality measure score for comparison with the organizational quality measure score and UDS benchmarks (Hwang, 2019). This project addresses these two interventions with preintervention comparison rates and updates as the EHR data updates.

Woudstra & Surmond (2019), Wilemse et al. (2022), and Sepucha et al. (2023) provided patient-centered conversational pursuits associated with improved uptake. The former

researchers found that encouraging the patient to choose using words to convey that 'the best test is the one that gets done' was effective for getting patient buy-in. This nudges patients frozen in indecision who may want to put off decision-making until later, hoping to feel more comfortable with colonoscopy 'next year.' Wilemse incorporated motivational interviewing, an enhanced recommendation from the provider to the patient found to yield self-efficacy in the patient's ability and motivation to perform the screening, agreeing with Chan & So (2021). El Sayad et al. (2021) additionally showed that beliefs, awareness, and screening behaviors were improved when the person providing the education was in a leadership role, focusing on the advantage of the nurse practitioner's involvement in this initiative. Wilemse applied the concept of shared decision-making to CRCS choices with success. This project will teach nurse practitioners the use of phrasing that improves outcomes and utilizes shared decision-making with a patient-generated preference form. This way, the nurse practitioner can utilize patient-centered priorities and patient risk level to order the most appropriate test. The use of nationally accepted guidelines for CRCS risk-factor grading is vital when offering options.

Patient reminders were a recurrent theme among studies that showed improved screening percentages. The studies showed different means of outreach. Green (2022) utilized calls, Coronado et al. (2018) compared live calls, automated calls, texts, and written letters with portal emails for patients who had them, Wilemse et al. (2022) delivered text messages after one week and a call after two, and the 2018 review by Davis et al. found no significant superiority between phone or text reminders, both worked equally. Usual care at the FQHC already consists of a reminder call to patients who have not yet returned their tests. Since this is effective in the evidence, there will be no change to this established workflow, but consistency will be encouraged as a priority and an electronic and paper log will be provided (see Appendix H).

Lastly, accessibility and convenience were factors in multiple studies. Green et al. (2022), Wilemse et al. (2022), and Davis et al. (2018) all had conclusions that highlighted the importance of convenience. Methods that placed the test in the patient's hands by mailing or that combatted complex steps by addressing and stamping them for the patient were successful. This project will make kits available in clinics or by mail. Cologuard comes preaddressed with postage satisfied, while FIT is lab-addressed with postage paid or can be dropped off at the clinic or in a mailbox. Other methods to improve convenience will rely on the nurse practitioner to request the gastroenterologist to allow patient input in scheduling of the colonoscopy. This aspect of convenience will be requested but is not guaranteed because it relies on influences outside the nurse practitioner's control, but the patients will be encouraged to request the procedure at a time that will minimize barriers to attendance.

Conceptual Framework

The conceptual model for this scholarly project (see Appendix A) is the Iowa Model of Evidence-Based Practice. The first of the ten steps to implementing evidence-based practice is the trigger (Titler & Adams, 2010). The trigger for this is problem focused. The Centers for Medicare and Medicaid has a Uniform Data System (UDS) which provides a standardized means of reporting annually the statistics of healthcare centers that receive federal funding. One of the measures of UDS is a calculation of the percentage of patients an organization sees that are age 50-75 who have had appropriate colorectal cancer screening (CMS, 2023). The Centers for Medicare and Medicaid Services requires patients 50-75 with at least one reportable visit in the 12-month period to have had an appropriate screen in the 10 preceding years, and it be recorded in the electronic health record (EHR). This includes the provision of an assessment, an order or referral if not yet screened or due for screening, documentation of the results, and further workup

if appropriate. The health centers use their EHR to extract the reports automatically. The latest known record from the UDS of CRCS rates among all federally qualified health center patients was in 2021, and it was 41.9 percent (ACS, 2023). The national percentage among all patients was 59 percent. (ACS, 2023). This FQHC organization cares for over 87,000 patients, so the number of patients that would potentially benefit from this initiative to improve CRCS is large. They have also received a grant, the American Cancer Society's 2023 Prevention and Screening Intervention, which provides the organization with $20,000 to focus on CRCS. The ACS has set a 22 percent goal of reporting CRCS for their grant recipients.

The UDS requires reporting of CRCS to meet quality indicators and, eventually, to measure pay for performance, so revenue is directly tied to meeting and documenting these goals. The current rate of reporting for this FQHC among the 32 clinics participating is between 1-28 percent. This trigger identifies a priority within the organization. There is a gap in the number of patients who are eligible for CRCS and the ones who have received screening or who have reported it. Staff are either not assessing or failing to document the screening status of patients in the target age range and as a result, the organization is not meeting the Merit-Based Incentive Payment System (MIPS) threshold or achieving the threshold set for receiving the American Cancer Society's (ACS) grant for 2023, thus affecting future grant allocation.

A literature search and synthesis were undertaken. Results include evidence-based practice guidelines for screening and evidence-based literature for communicating the importance to patients, proven efficacy with shared decision-making, and tools for staff education for implementing a screening initiative. There is organizational support to improve practice in this area. A practice pilot was developed and implemented, and the results were monitored. Using PDSA, successive trials refined and modified clinical workflows throughout

the pilot period. This will be evaluated at the end of the trial. If it is appropriate for adoption, it will be continued, and if there is enough data to support a change in practice, the results will be disseminated to management of the organization, to assist all clinics in meeting the CMS requirements for MIPS and the ACS, thus securing revenue for the next year's cancer prevention initiatives.

Summary

In summary, this project links grade 1 recommendations for CRC cancer screening to evidence-based interventions to improve uptake and reporting in the outpatient setting (see Appendix B). This quality initiative was performed using a toolkit. We know there is moderate improvement in screening using each intervention in isolated settings, but this project looked at the result of combining multiple components for more robust outcomes. Considering the importance of CRCS, it is appropriate to link proven interventions to multiply the results. The data used to inform the various components of the toolkit gives compelling evidence for the impact of healthcare organizations removing barriers to screening and documenting with purpose, thus increasing access and reporting of their conformity.

SECTION THREE: METHODOLOGY

The proposal for this project is the implementation of a toolkit to improve the screening and documentation of CRCS among 45–75-year-old patients. Though UDS measures 50–75-year-olds, the newest evidence-based guidelines will be benchmarks for this evidence-based project. It included several data-driven patient and clinician-focused strategies, including staff education, clinic flow interventions, patient educational handouts, and a clinic tool to target appropriate patients with the most beneficial screening type. Rates of documented screening pre-intervention were compared to post-intervention rates.

Project Design

This project was undertaken as a quality improvement/ evidence-based practice initiative at the FQHC and, as such, was not formally supervised by the Liberty University Institutional Review Board. This proposed study employed a quasi-experimental, quantitative design. Results were assessed using a pre-implementation and post-implementation design with a non-equivalent control group to compare the effect of the toolkit on colorectal cancer screenings. Another clinic in the same rural town managed by the same organization served as the non-equivalent control group and receive no added interventions at this time. Statistical methods to provide control for any confounding variables in the clinic sites and among the patients at these sites were employed.

Measurable Outcomes

The outcomes that were measured following this study included an increase in colon cancer preventive screening and reporting, which reflected improved adherence to assessment of patient statuses, ordering or referring for screening as appropriate, and documentation of results. The data collected before the intervention was the number and percentage of patients in the 45-75 age range eligible for CRCS who have up-to-date data in the EHR that satisfies this quality measure. This project aimed to assist the organization in realizing an overall increase in CRCS of 10% in 2023. This project was implemented in the late second and early third quarter of 2023, to help as they intensified their efforts to finish the year at goal. If implemented system-wide, this toolkit could potentially align all thirty-two clinics to meet the organizational goal of at least a 10% annual increase. A secondary but important measurable outcome was an increase in staff knowledge, as noted by a change in pre and post-test scores with staff education before the start

of the initiative (see Appendix L and Appendix M). A third measure was adherence to national guidelines and standards of care.

Setting & Population

This study occurred in a rural, federally qualified health center in eastern North Carolina (see Appendix F for organizational support letter). The site is one of thirty-two owned by the same organization. The clinic takes federally, privately, and uninsured patients who pay on a sliding scale fee system. Of the organization's *total* patient population, in 2022, 36% were Medicare and Medicaid dually eligible, 26% were Medicaid only, 35% were Medicare only, 33% had private insurance, and 2% were uninsured. The 2022 demographic distribution of the organization's patients was 31% white, 23% Black, 16% Latino, 4% or less of each other race and 25% unreported. This clinic is in a town in Wayne County with a population of 4,200. The control cohort clinic is in the same town. They each have only one nurse practitioner. The median household income is $64,008, with a 23.4% poverty rate, a 58% minority rate, 84% speak English, and 78% have at least a high school diploma (World Population, 2023).

The intervention will be directed at the clinics. Each clinic in the study comprised a site leader, a nurse, a family nurse practitioner (FNP), and front desk staff. Therefore, clinic size should not confound the results. The pilot clinic has 2033 patients, and the cohort has 2270, so the patient sample size is similar. Onsite interpreter services and laboratory services are provided at both. The family nurse practitioner (FNP) at the intervention clinic has four years of experience as a provider, and the FNP at the cohort clinic also has four years of experience. Thus, location and level of experience will not be a confounder. Recruitment was performed by an email invitation to the clinic that is in the closest proximity to the organization's headquarters;

thus, convenience sampling was utilized. No compensation was provided to the clinician or staff members for participation.

The organization's quality projects registered nurse is the mentor for the project. She oversees keeping data on all their quality measures and is also the risk manager. She is a retired nurse who has returned to work full-time with the company to help address gaps. She was instrumental in moving project implementation forward and accessing key data from reports and the EHR throughout the pilot period. This researcher was also granted access to the necessary data through the EHR. Other stakeholders in the interest of CRCS include the education director, the clinical quality and compliance coordinator, and the clinical services director. These nursing staff members also served on the ACS QI team to advance CRCS and are vested in meeting the screening measure goals.

Ethical Considerations & Christian Worldview

This study did not involve direct contact with patients. There are no direct benefits for the participating clinics, but it will benefit the healthcare organization that owns the clinics by upholding national guidelines for standards of care in the form of greater reimbursement from CMS, and the ability to continue to receive funding for cancer screening initiatives from the ACS. No patient information will be used by the researcher. Patients of the cohort are not being denied care or treated unethically. Their nurse practitioner continued CRCS and documenting as usual, along with the other thirty clinics belonging to this organization, but to test the benefit of adding the toolkit, the results needed to be compared to a similar clinic where the toolkit was not implemented. The control clinic will have the opportunity to use the toolkit later. The proposed study received approval from the Institutional Review Board (IRB) before initiating any patient interventions to ensure ethical practices were followed (see Appendix C for CITI training).

This initiative aligns with the Biblical mandate to love and care for one's fellow man. Ezekiel 3:18 requires that God-fearing people warn others of danger effectively, and if they do not, the blood of that person rests in their hands (*English Standard Version Bible*, 2001). By extension, failing to offer screening and promptly treat abnormal findings represents failing to warn a fellowman of potential impending danger. Also, by applying and appealing to a patient's desire to live a healthy life, the Bible has practical guidance for treating the body as the temple of the Holy Spirit (*English Standard Version Bible*, 2001, 1 Cor. 6:19, 20) by issuing advice about avoiding harmful practices such as smoking, heavy drinking, inactivity, and overindulgence of unhealthy food leading to obesity, all of which can contribute to the development of colorectal cancer. While discernment is needed, applicable Bible truths can be discussed with patients who revere it as the Word of God with an appeal to its omniscient author as the Source of Life and Preserver of it. Either inductively or deductively, the Bible can be used as a basis for these provider-based or patient-based interventions to promote CRCS compliance.

Data Collection

Data was retrieved from the quality projects nurse using the EHR dashboard. Access to these health information systems was granted through the organization's information department after confirming the completion of HIPAA through Castle Branch. Various searchable reports were generated for use in the statistical analysis from these two dashboards. This allowed visualization of rates of screening to be documented before and after the intervention with interval updates. Claims update the data, so the benefit of what is done now may take weeks to make it to the dashboard to measure change. Because of this, there needed to be a lag in the analysis of data to track change after the completion of the intervention. This was controlled by

selecting a window that started 1 week after initiation of the toolkit and ended 2 weeks after the completion of the pilot.

Tools

From the literature review, several elements that aided in the uptake of CRCS were emphasized. These were used to generate training for the staff (see Appendix J and N). An in-person lunch and learn was scheduled onsite for staff education. CRCS guidelines used by UDS followed the USPSTF guidelines and included colonoscopy, flexible sigmoidoscopy, fecal occult blood testing, Cologuard, and CT. The options provided at this health center include colonoscopy, Cologuard, and FIT. Nurse practitioners were reminded of how to satisfy measures in the EHR, how to initiate shared decision-making discussions using the patient preference area of the handout, the importance of screening the patient, and a review of each testing option and frequency needed. All toolbox components were explained to the nurse practitioner and staff. Organizational revenue maintenance as an added benefit to meeting requirements was also discussed. The nurse practitioner was shown her current CRCS rate compared to organizational rates and the goal.

Administrative staff received instructions about their part of the initiative, including printing out the daily census of patients that have not met their screening goal, and ensuring completion of the patient tool and preference section of the form prior to seeing the nurse practitioner (see Appendix G). The questionnaires given for patient use were reviewed by staff. Patient educational materials from the American Cancer Society (English) and the CDC (Spanish) used for this initiative were on hand during the lunch and learn. Additional patient information will be simple and gist based as several studies have shown that when it comes to

health information, ‘less is more,’ and that patients are turned off by the multitude of numerical facts (Smith et al., 2015).

Links to online video instructions for in-home screening were printed on the patient questionnaires to take home, along with a QR code to access these electronically. This ensured that patients were ready to talk to their nurse practitioner after reviewing options and considering family history when they reach the exam room. A clear path to referral and ordering was reviewed with providers. They were encouraged to discuss scheduling with patient input with the gastroenterologist they refer to most frequently. A pretest and posttest were administered to assess the effectiveness of staff education (see Appendix M). It included the material discussed during the lunch and learn and the components of the toolkit. A review of incorrect responses was addressed at the lunch and learn following the posttest. Copies of the material discussed was left with attendees.

Personnel

The researcher provided education and training for staff and ensured the necessary documents were on site. Inventory of the site’s FIT tests and the model Cologuard test was performed. The quality and special projects nurse at the organization pledged assistance with data collection and analysis before, throughout, and after the project. Improvement in scores would be of special interest to her department for the possibility of using a toolkit to improve additional benchmarks in the future. No additional staff was required.

Budget

The budget for implementing the colorectal toolkit fell within the organization’s grant from the ACS, and support from the organization for the use of necessary resources was given. The cost comprised printed educational material, patient handouts and survey forms, and lunch

during the educational session. Lunch was boxed and totaled less than $60.00. The researcher covered snacks during the midpoint and post implementation visit. The organization agreed to cover the cost of bulk printing and the luncheon with ACS grant funding. If it effectively improves CRCS and reporting, the project's cost in the other thirty-four clinics will be similar but adjusted based on clinic size and patient population. Education is necessary for existing staff members organization-wide but can be incorporated into new hire orientations over time, so the cost of the training luncheon will eventually be eliminated.

At $0.10 per copy, the patient cost of the handout and survey is $0.20 per patient. The number of unscreened patients at the intervention site who were eligible was 363. The total of patient printing which was supplied by the organization would have been $72.60. The educational material for the nurses had five pages, so $1.00 per staff member. The ACS awarded $8,000 organizationally as gift cards, specifically for gas, which the organization chose to provide in $20 increments as an incentive for patients completing CRCS. This amount was not advertised because it was divided among the thirty-two clinics, so there were only a few to provide at each site, but the nurse practitioner had the option of providing them to patients while supplies lasted. The staff received CRCS bracelets at kickoff to remind them to ask everyone. These were obtained for $3.99 each, covered by the researcher. A binder and a thumb drive were obtained for staff preference of using a paper or digital spreadsheet version of the CRCS Log. The cost of these by the researcher was negligible.

Step by Step Intervention(s) and Timeline

The timeline and step-by-step interventions for the project are outlined (see Appendix C). The proposed timeline allowed adequate time for data collection, analysis, and evaluation after implementation for the eight-week pilot window.

SECTION FOUR: RESULTS

Data Analysis

The project results showed improvements in each of the three domains: staff education, colorectal screening uptake, and adherence to North Carolina's screening benchmarks (See Appendix Q). The data collected during the 8-week project was collected and analyzed. The staff education was evaluated using a statistical chi-square test. This compared the scoring of the staff's CRCS knowledge before and after the educational lunch and learn intervention using an expected score and then measuring the difference in the actual score; scores were not matched to specific participants to preserve confidentiality. The uptake of colorectal cancer screening in each clinic was evaluated using the statistical chi-square test. This was an appropriate test because it evaluated what each clinic's uptake was in the eight weeks before the implementation, and created an expected rate for the intervention phase that followed the same course and compared that to the actual screening during the eight-week pilot to see if there was a difference, or a significant increase over what would have naturally occurred. It also allowed the opportunity to evaluate any changes in scoring that happened for confounding reasons other than the intervention. The adherence to state guidelines was analyzed by comparing pre- and post-interventional screening percentages to NC's benchmark. A statistician was consulted to assist in the final analysis of the data.

Measurable Outcome 1

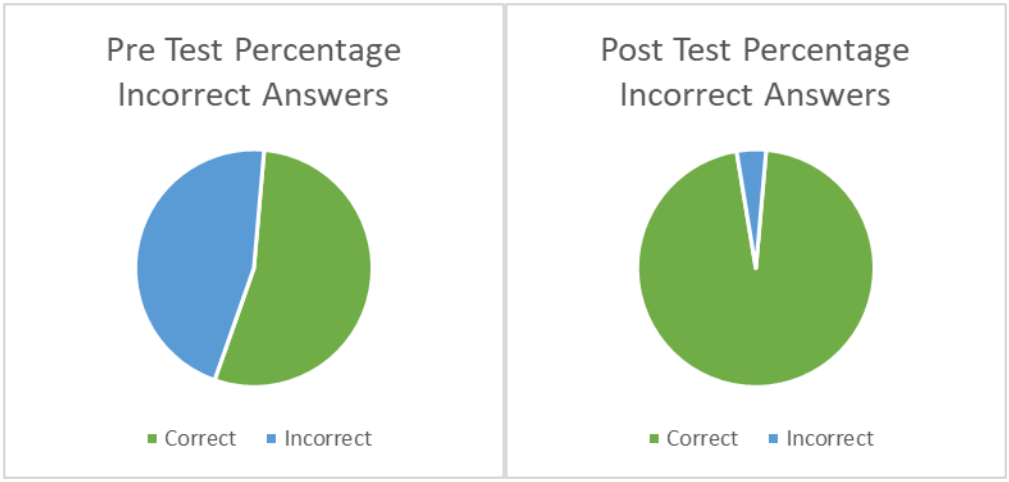
The lunch and learn staff training on September 5, 2023, was attended by 8 staff members. Five staff members participated in the pretest, and three participated in the posttest. The reason for this is unclear, though there were technology difficulties. To maintain

confidentiality, the tests were anonymous and thus unmatched. The staff had 54 percent correct answers in the pretest and 96 percent in the posttest. A chi-square analysis was performed, leading to rejection of the null hypothesis that education would make no difference.

Qualitatively, the staff was engaged during the training and after the session was complete. There was a verbal review of the quiz following the posttest, and staff displayed confidence in their responses. Incorrect test answers were addressed until they voiced understanding. The researcher and mentor stayed behind to assist the staff members in how they would each implement their portion of the toolkit.

Figure 1

Staff Education Results



Measurable Outcome 2

Colorectal cancer screening uptake rose from 34 to 40 percent with the toolkit's implementation at the pilot clinic. Screening rates at the cohort clinic declined from 25 to 22

percent. The null hypothesis was that the toolkit would make no difference in screening uptake. Chi-square analysis proved that the null must be rejected.

Figure 2

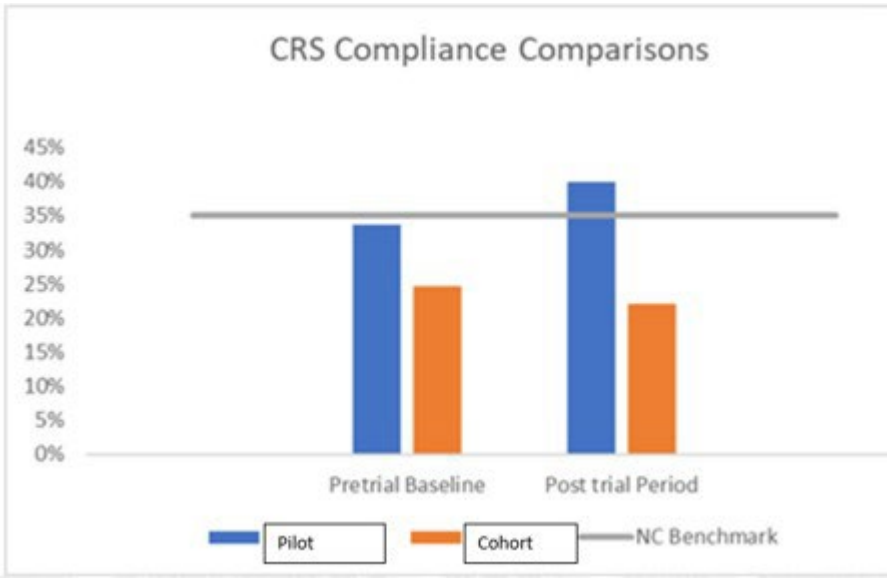
Screening Percentage Results

Measurable Outcome 3

The last measure of the project was adherence to state colorectal cancer screening benchmarks. North Carolina's colorectal cancer screening benchmark this year is 35 percent. The pilot clinic's rate rose from 34 percent to 40, thus meeting the statewide benchmark during the period of toolkit use. The cohort clinic did not meet the state benchmark, with a higher score in the eight weeks before the trial period which dropped. Upon receipt of the ACS grant, the organization's stated goal was to increase CRCS by 10 percent this year. The pilot clinic's first-quarter screening rate was 28 percent. The toolkit augmented their efforts, and they exceeded their goal, improving the rate by 12 percent at the end of the trial, with many more weeks remaining in the year to further increase it.

Figure 3

Comparison with Statewide Benchmarks



SECTION FIVE: DISCUSSION

Feasibility Analysis

This toolkit is an inexpensive method of improving patient outcomes through adherence to evidence-based guidelines for screening and prevention. It has organizational implications of increased resources and compliance. This toolkit was effective with local implementation and economical enough that organizational implementation makes sense. From a practical standpoint, there are very few changes to the clinic's current patient flow. It may take time to develop the habit of providing screening forms at the front desk and reviewing them in the exam room, but it can become habitual within a short time. Reminders may prove beneficial for this. No additional staff was required, no technology that is not already accessible was needed, and due to the ACS grant and Cologuard allocation, patients do not pay more out of pocket. It helps

the organization meet its goals with the benefit of increased funding for meeting benchmarks and less shared savings. Implementation can strategically be performed by the clinical educator, site leader, a video, or protocol booklet in-service, or by training one person from each clinic as a super-user who could educate other staff members at their respective sites.

Cost effectiveness analysis

First, the benefit in cost-effectiveness to the healthcare system should be considered. Patients who have CRC and are screened and identified while the cancer is localized fare much better (ACS, 2023). The ACS estimated that there would be 153,020 newly diagnosed colorectal cancer cases this year and 52,550 deaths (ACS, 2023), not to mention the quality-adjusted life years (QALY) for the 100,470 survivors. As mentioned, the cumulative risk of CRC in the population is 1.51% in men and 1.12% in women (Rawla et al., 2019). Applied to the population at this organization with 37,841 male patients and 50,053 females, the possible incidence of men and women could be 571 and 561, respectively. The personal and national burden of diminished QALYs for these 1,132 patients and potential mortality from this organization alone cannot be overemphasized.

Early onset younger patients are more likely to be diagnosed with advanced stages of cancer (Siegel et al., 2023) stressing even more the importance of screening all eligible patients beginning at age 45 as the recent guidelines recommend. The avoidable loss of life from this detectable, treatable disease is abysmal. It has been emphasized that CRCS can identify patients with suspicious lesions, which can be removed before they turn into cancer or metastasize. In a systematic review by Bhimani et al. (2022), the average cost to treat localized CRC was $12,346 but rose to $293,461 when metastasized and if systemic therapy was used, increased to almost

$300,000. The healthcare and societal cost-effectiveness analysis for using a multi-interventional toolkit to screen and facilitate removing precancerous polyps is well worth the effort and cost.

Sustainability

Lastly, the direct organizational cost-effectiveness analysis of adding this toolkit at the study site is important. The cost of adding this toolkit to the clinic routine is minimal compared to potential patient gains and resource funding gains. It is approximately $0.20 per patient and $1.00 per staff member, and even if a lunch is included, would be more cost-effective than paying their salary for an hour during scheduled work time. The benefit to the organization is continued ACS cancer prevention grants, which was $20,000 this year, renewable if it is determined that they are meeting the goals of the grant, which they did at the pilot clinic. They also receive coverage from the insurance of the patients for performance of the screening, community grants aimed at routine care of rural underserved patients, and funding as an accountable care organization (ACO) by meeting CQMs, which include CRCS. The benefit of meeting this will continue to *rise* as organizations are paid on a value-based model with incentives for meeting benchmarks versus being penalized for failure. The cost of implementation will continue to *fall* as staff becomes accustomed to the small changes in patient flow. It is a small price to pay for potentially life-saving results.

Evaluation

This project was well supported by the organization because it fulfilled one of their objectives. However, there were a few plans that did not follow through as expected. The organization owns its own EHR, Cloud Craft. The plan to make changes to the EHR was not in alignment with the information technology department's priorities, and thus, the plan to make the patient's screening status more accessible in the electronic chart did not occur prior to the

start of the pilot. It is still on a list of planned upgrades because value has been pointed out but was not in place when the pilot began.

A second barrier that occurred during the pilot was that clinic the pilot was planned to be implemented in contracted COVID-19 the day of the Lunch and Learn. To prevent further delays, the cohort clinic was used as the pilot clinic. This only had implications since the original clinic had lower rates of screening and it was hoped that the pilot would improve scores in that clinic. However, the tool can now be used in any clinics the organization desires in addition to their current standards of care.

Lastly, the inability to maintain front desk staffing at the pilot clinic presented a problem. Staffing at the 4-week midpoint had completely turned over, and the researcher had to in-service new staff. At the end of the trial, two of those new staff had left. The clinic did not run out of the initial supply of forms, reflecting that training of new staff did prioritize distribution of the education and questionnaires, understandably. Since this was the first touch point of the toolkit, it is possible that the pilot would have seen greater results had the clinic been able to maintain consistent staffing. Short-staffing is an issue in many clinics in the post-COVID era, and duplication of this pilot should consider utilizing staff-sparing interventions in future toolkits. One way this could be addressed is by displaying a self-serve center at check-in from which patients could pick up the appropriate screening and education forms for themselves.

Significance and Implications for Practice

This toolkit has major implications for practice. It can provide a clear path to meeting organizational and national goals. Each intervention had statistical significance for improving CRCS scores, and as a toolkit with grouped interventions, it can improve the health of the population by providing improving early detection of CRC. The USPSTF, ACG, ACS, and CDC

have all made CRCS a national priority. Aligning the organization with these goals saves lives. The health of the 87,000 plus patients seen by this FQHC depends on following evidence-based guidelines and documenting them to receive credit for their efforts. This initiative provides a way to meet these objectives.

Dissemination Plan

The evidence supports use of this toolkit to improve colorectal cancer screening in the primary care setting. The project data, outcomes, and analysis will be communicated to stakeholders by a PowerPoint presentation. It is hoped that they will recognize the benefit of using the toolkit to increase CRC screening at their other clinics. The researcher will be available to assist with disseminating and training staff as needed. Duke University Health Systems has a population health management office which has requested the PowerPoint and presentation will be made at their monthly staff meeting. Reporting will be shared with Liberty University professors and students by submission to Scholar's Crossing repository.

Conclusion

This project has brought light to the incidence and prognosis of late-stage colorectal cancer. It has explored the benefits of early detection and the methods of screening. The toolkit, designed using evidence-based practices conjointly, can potentially prolong life by initiating early detection, diagnosis, and subsequent treatment. The ease of use and facilitation of shared decision-making will appeal to nurse practitioners who, despite diligence, have limited time to review and apply all appropriate quality metrics during the patient encounter. The prospect of meeting clinical quality measures as a value-based reimbursement methods continue will appeal to operations managers seeking ways to promote compliance. This toolkit has proven

effectiveness for meeting organizational screening goals efficiently and can lead to staff satisfaction and improved patient outcomes.

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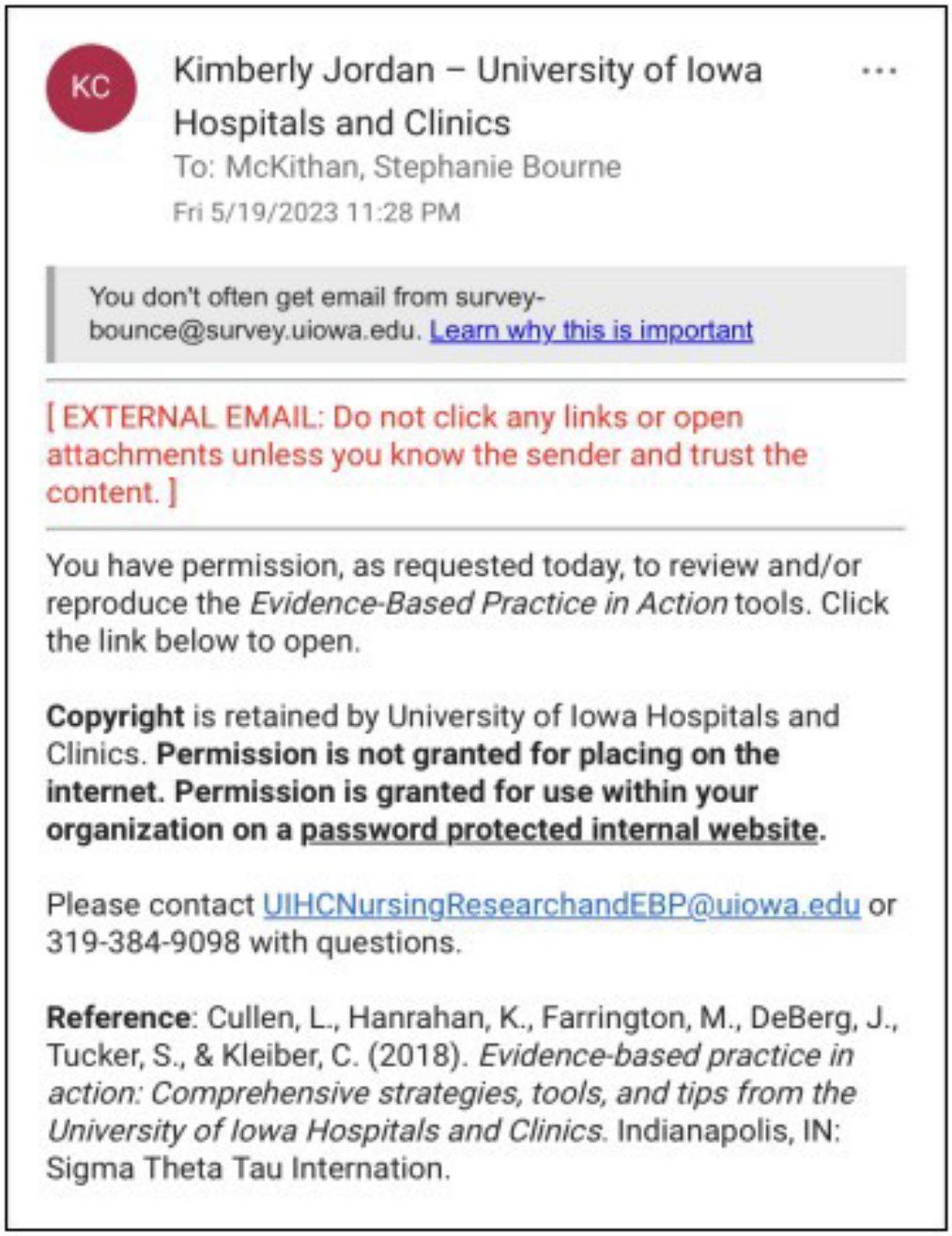
Appendix A. Approval to Use the Iowa Model.



KC

Kimberly Jordan – University of Iowa Hospitals and Clinics

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Reference: Cullen, L., Hanrahan, K., Farrington, M., DeBerg, J., Tucker, S., & Kleiber, C. (2018). *Evidence-based practice in action: Comprehensive strategies, tools, and tips from the University of Iowa Hospitals and Clinics*. Indianapolis, IN: Sigma Theta Tau Internation.

Appendix B. Evidence Table

Article Title, Author, etc. (Current APA Format)	Study Purpose	Sample (Characteristics of the Sample: Demographics, etc.)	Methods	Study Results	Level of Evidence (Use Melnyk Framework)	Study Limitations	Would Use as Evidence to Support a Change? (Yes or No) Provide Rationale.
Coronado, G., Rivelli, J., Fuoco, M., Vollmer, W., Petrik, A., Keast, E., Barker, S., Topalanchik, E., & Jimenez, R. (2018). Effect of reminding patients to complete fecal immunochemical testing: A comparative effectiveness study of automated and live approaches. *JGIM: Journal of General Internal Medicine*, *33*(1), 72–78. https://doi.org/10.1007/s11606-017-4184-x	Compare the effectiveness of reminders to complete the previously mailed FIT test	2010 adults aged 50-75 due CRC screening that used Sea Mar health centers in WA	RCT. Compared effectiveness of a reminder letter, automated call, live call, text message, and combinations to see which yielded > FIT returns. Random selection	Live phone call yielded higher return than the (written) letter or text reminders did	Level 2 Randomized control trial	It is possible texts were not delivered to phones with texting, letters may have not all been returned if non deliverable. Also performed in one locality in WA	Yes, large sampling, diverse, and provided evidence of the best method to remind patients to complete their screening which is by live call

Davis, M., Freeman, M., Shannon, J., Coronado, G., Stange, K., Guise, J., Wheeler, S., & Buckley, D. (2018). A systematic review of clinic and community intervention to increase fecal testing for colorectal cancer in rural and low-income populations in the United States - How, what, and when? *BMC Cancer*, *18*, 1–N.PAG. https://doi.org/10.1186/s12885-017-3813-4	To determine how implementation strategies influenced the uptake of FIT and FOBT in rural low-income populations	Study inclusions interventions to increase CRC screening 1998-2016	Systematic review and qualitative synthesis of fifty-six studies	When using kits by direct mail, preaddressed stamped envelopes, reminders, and in-clinic distribution of kits increased uptake of screening in the clinic-based patients	Level 1: systematic review	Rural setting, prior to Cologuard, low-income vs working class in this project, implementation strategies were limited	Yes, the actions that increased screening in the studies with highest yield were discussed and are replicable for the project

Green, B., Anderson, M., Cook, A., Chubak, J., Fuller, S., Meenan, R. T., & Vernon, S. W. (2022). A centralized program with stepped support increases adherence to colorectal cancer screening over 9 Years: a randomized trial. *Journal of General Internal Medicine, 37*(5), 1073–1080. https://doi.org/10.1007/s11606-021-06922-2	Examining the effect of mailed FIT tests, info for scheduling colonoscopy, follow-up phone calls, and nurse navigation	4,653 eligible 50–74-year-olds in a Washington State health care system	Randomized control trial assigning mailed FIT tests vs usual care	57% CRCS increased to 69% screening in the intervention group over usual care control group. Mailed test with follow-up phone	Level 2 RCT	Did not examine in-house distribution of tests with provider recommendation and encouragement to complete	Yes, while this QI project will not mail out tests, it does give proof that access and convenience will increase uptake of CRCS

	on CRCS rates.			calls yielded the most return			
Hwang, A. S., Harding, A. S., Chang, Y., O'Keefe, S. M., Horn, D. M., & Clark, A. L. (2019). An Audit and Feedback Intervention to Improve Internal Medicine Residents' Performance on Ambulatory Quality Measures: A Randomized Controlled Trial. Population Health Management, 22(6), 529–535. https://doi.org/10.1089/pop.2018.0217	Examining the effect of providing audit and feedback of performance on meeting quality measures	Ninety-six medical residents in Boston, MA	A randomized half of the residents were shown their individual quality measures compared to the target goal for the practice	The increase form 72.5% vs. 64.6% was a statistically significant improvement in CRCS rates and increased the organization's composite quality score.	Level 2 RCT	Only took data from residents in an internal medicine program in one school in MA, may not be generalizable	Yes, this one addition to the toolkit may help providers work harder to meet organizational benchmarks.

El Sayad, H., Ramzy Ahmed Atalla, H., & Mostafa Amer, H. (2021). Effectiveness of nurse-led intervention on adults' health beliefs and screening behaviors toward colorectal cancer. *Egyptian Journal of Health Care, 12*(2), 96-113.	To observe the effects of a nurse led educational interventio n on patient screening	140 patients in outpatient Egyptian clinics	Questionnai re and survey pre and post intervention	Statistically sig improveme nt in study group from 5.28 to 7.93 in health beliefs p=.000, screening behaviors and CRC knowledge	Level 3 Quasi experiment al	Was performed in another country, culture toward medical experts (and women) may be different there	Yes, Leadership position of the one recommendi ng the screen was important in patient decision to screen
Mojica, C., Gunn, R., Pham, R., Miech, E., Romer, A., Renfro, S., Clark, K., & Davis, M.(2022). An observational study of workflows to support fecal testing for colorectal cancer screening in primary care practices serving Medicaid enrollees. *BMC Cancer, 22*(1), 1–10. https://doi.org/10.1186/s12885-021-09106-7	Examined different tactics for increasing CRCS	Nine primary care practices in Oregon	Surveys, observation al visits, and informal interviews	Practices with higher CRCS had MAs discuss and review FIT/FOBT with patients describing options and instructions.	Level 4 correlationa l design	Only OR clinics, only first-time screeners, only Medicaid enrollees, may not generalize	Yes, this supports the MA staff explaining options, MAs ordering or distributing tests, review of chart prior to visit and generating list of patients due for screening

Sepucha, K., Valentine, K., Atlas, S., Chang, Y., Fairfield, K., Ha, J., Leavitt, L., Lee, V., Percac-Lima, S., Richter, J. M., & Simmons, L. (2023). Getting patients back for routine colorectal cancer screening: Randomized controlled trial of a shared decision-making intervention. *Cancer Medicine*, *12*(3), 3555–3566. https://doi.org/10.1002/cam4. 5172	Determine if a shared decision outreach would improve CRCS	Eight hundred patients 45-75 years of age who had CRC screening cancelled due to COVID	Randomized controlled trial	Higher screening rates at 6 months in intervention group (43% vs 25%)	Level 2 RCT	May not generalize to non-pandemic era since no mass cancellation and only one call was attempted which lowered intervention numbers	Yes, shared decision making is effective and shows patient-centered care

Soriano, C., McGarrity, T., Zhu, J , Loloi, J., Peiffer, L. & Cooper, J. (2021). An electronic questionnaire to survey colorectal cancer screening status and identify high-risk cohorts in large health care organizations. *American Journal of Medical Quality, 36* (3), 163-170. doi: 10.1177/1062860620937236.	To develop and utilize an electronic questionnaire validated for assessing CRC status and risk level.	2,638 patients at Penn State Medical Center and Medical School	Survey taken from patients through outreach from DHHS	878 high-risk individuals were identified, 23% were not up to date on CRCS	Level 6 Descriptive design	Inflammatory bowel disease personal history was not assessed in the survey	Yes, the questions were a good example of thoroughness in decision making for colonoscopy vs home stool sample screening. Validated tool for research.

Walker, T., Risendal, B., Kegler, M., Friedman, D., Weiner, B., Williams, R., Tu, S., & Fernandez, M. (2018). Assessing levels and correlates of implementation of evidence-based approaches for colorectal cancer screening: A cross-sectional study with federally qualified health centers. *Health Education & Behavior, 45*(6), 1008–1015. https://doi.org/10.1177/1090198118778333	To assess the impact of evidence based activities and clinical correlates on improved CRCS rates	59 FQHCs in CA, CO, GA, MO, SC, TX, and WA	Cross-sectional and descriptive analysis of clinics and survey of clinic characteristics	The ease of retrieving CRC status from EHR and training for 1:1 education correlated most with higher rates of CRCS	Level 4 correlational design	Staffing level in various clinics varied, and it was considered important in being able to reach implementation goals.	Yes, ease of retrieving CRC status from EHR and 1:1 education training most important.

Willemse, J., Jadalla, A., Conahan, L., Sarff, L., & Brady, M. (2022). GetFIT for CRC: Nurse practitioner–led program to improve colorectal cancer screening. *The Journal for Nurse Practitioners, 18*(9), 968-975. https://doi.org/10.1016/j.nurpra.2022.08.001	To design and implement an EB bundle that improves CRCS rates	QI implemented in 5 PCP clinics in CA	Quasi-experimental design	45% rate rose to 65% rate after 6 months implementation	Level 3 evidence	Did not target 45–49-year-olds initially and did not target uninsured as the FQHC will	Yes, will be implementing similar interventions
Woudstra, A., & Suurmond, J. (2019). How narratives influence colorectal cancer screening decision making and uptake: A realist review. *Health Expectations*, *22*(3), 327–337. https://doi.org/10.1111/hex.12892	To assess what narratives work for patients making decision on CRCS	Inclusion articles with narrative interventions for CRCS. 1401 initial articles trimmed to 15 included	Increased screening uptake and self-efficacy with person-centered narratives used in CRCS discussions	in-formed decision making through actively promoting the message "The best test is the one that gets done"	Level 1 Systematic review	Narrative intervention studies. Small inclusion result	Mildly. Personalizing the discussion to the audience is important when shared decision making is used.

Appendix C. Timeline for Project

Completion Date	Planning	Pre-implementation	Implementation	Evaluation
June 20, 2023	Obtain approval from site leaders to pilot project in the test clinic	Completed		
June 20, 2023	Select ACS printed materials.	Completed		
June 27, 2023	Review clinic scores with Lynn. Audit 50 charts to find barriers and unintended documentation errors that hinder accurate reporting of CRCS so provider education can address this	Completed		
June 27, 2023	Create provider cheat sheet to summarize CQMs required on all applicable patients (including CRCS)	Completed Reviewed and disseminated by pt educator. Will also be in toolkit for clinics.		
June 27, 2023	Attend Cologuard training, learn how to order online for the upcoming allocation and get approval for clinics to have a demo kit.	Completed		

July 11, 2023	Complete staff education plan	Completed		
July 18, 2023	Complete clinic check-in forms in English. Give to Lynn for review and editing before Spanish interpreted	Completed		
July 18, 2023	Obtain a FIT test and ensure clinic has a Cologuard sample kit. Review for gaps in instructions.	Completed		
July 25, 2023	Discuss EHR enhancements to correct documentation discrepancies with project manager to see if amelioration is possible		Completed	
July 25, 2023	Finalize pre-and post-testing for staff	Completed		
July 31, 2023	Finalize all training materials and pre and post testing for staff	Completed		
August 1, 2023	Have patient questionnaire interpreted and peer-reviewed by a secondary bilingual interpreter	Completed		

August 1, 2023	Create the Survey Monkey pre/posttest for staff and staff Likert implementation survey.	Completed		
August 1, 2023	Create QR Code for patient instructional videos	Completed		
August 16, 2023	Submit IRB application. Complete PowerPoint Presentation. Present to DOO. Obtain IRB approval and site internal approval.	Completed		
8/29/23	Update site leader on initiative and send lunch options.	Completed		
8/29/23	Schedule staff lunch and learn. Order Lunches	Completed		
9/4/23	Update pre-implementation data	Completed		
9/11/23	Clinic Lunch & Learn training with staff. Pre and posttest scores collected. Trial run of intervention in clinic.		Completed	
9/11/23	Give nurse practitioner personal CQM rate.		Completed	
9/11/23	Clinic Kickoff. Be at clinic for kickoff and rapid		Completed	

	PDSA cycle improvements. Pilot begins.			
9/19/23	Track data 9/19-11/21/23 for claims lag.		Completed	
10/10/23	Midpoint: Check Dashboard for data updates. Calculate midpoint data from EHR for provider		Completed	
10/10/23	Meet clinic with snacks and rally. Give nurse practitioner midpoint data, encouragement		Completed	
11/7/23	Clinic pilot ends.		Completed	
11/14/23	Thank staff for completing pilot and provide treats and details of changes since implementation. Send implementation Survey Monkey to staff Request EHR access.		Completed	
11/21/23	Calculate endpoint data using a 2-week lag for claims. Compile survey data for statistician			Completed
11/21/23	Compile project data. Submit to statistician for analysis.			Completed

Spring 2024	Defend project. Disseminate finalized project & results to organization stakeholders, Duke Population Health, and submit written copy to Scholar's Crossing.			Completed

Appendix D. CITI Training Certificate

CITI PROGRAM

Completion Date 23-Jun-2023
Expiration Date 23-Jun-2026
Record ID 56675386

This is to certify that:

Stephanie McKithan

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

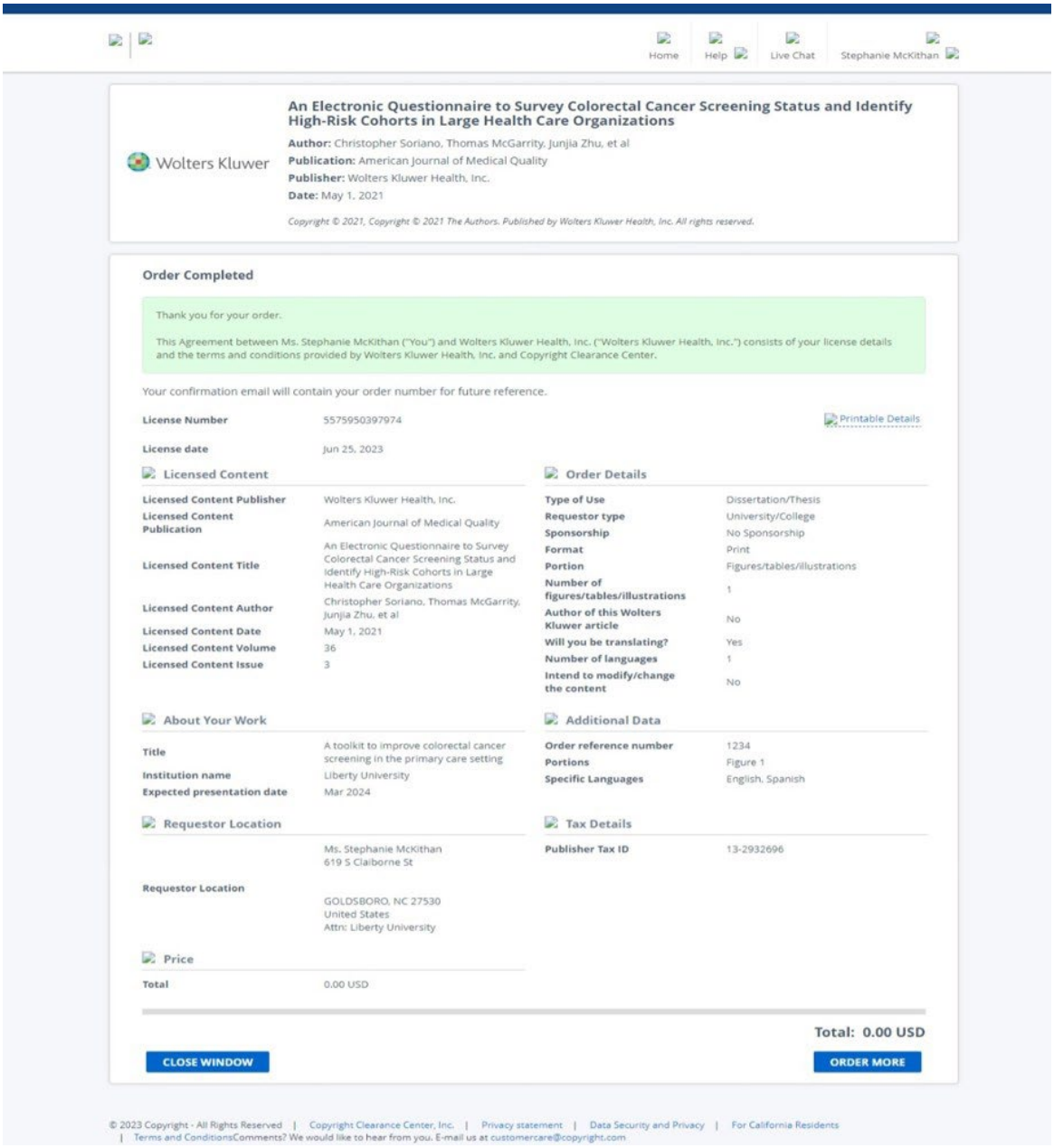
Biomedical Research - Basic/Refresher
(Curriculum Group)
Biomedical & Health Science Researchers
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Liberty University

CITI
Collaborative Institutional Training Initiative
101 NE 3rd Avenue, Suite 320
Fort Lauderdale, FL 33301 US

Appendix E. Permission to Use Screening Tool



Home Help Live Chat Stephanie McKithan

Wolters Kluwer

An Electronic Questionnaire to Survey Colorectal Cancer Screening Status and Identify High-Risk Cohorts in Large Health Care Organizations

Author: Christopher Soriano, Thomas McGarrity, Junjia Zhu, et al
Publication: American Journal of Medical Quality
Publisher: Wolters Kluwer Health, Inc.
Date: May 1, 2021

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Licensed Content Date	May 1, 2021
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Order Details

Type of Use	Dissertation/Thesis
Requestor type	University/College
Sponsorship	No Sponsorship
Format	Print
Portion	Figures/tables/illustrations
Number of figures/tables/illustrations	1
Author of this Wolters Kluwer article	No
Will you be translating?	Yes
Number of languages	1
Intend to modify/change the content	No

About Your Work

Title	A toolkit to improve colorectal cancer screening in the primary care setting
Institution name	Liberty University
Expected presentation date	Mar 2024

Additional Data

Order reference number	1234
Portions	Figure 1
Specific Languages	English, Spanish

Requestor Location

Requestor Location	Ms. Stephanie McKithan 619 S Claiborne St GOLDSBORO, NC 27530 United States Attn: Liberty University

Tax Details

Publisher Tax ID	13-2932696

Price

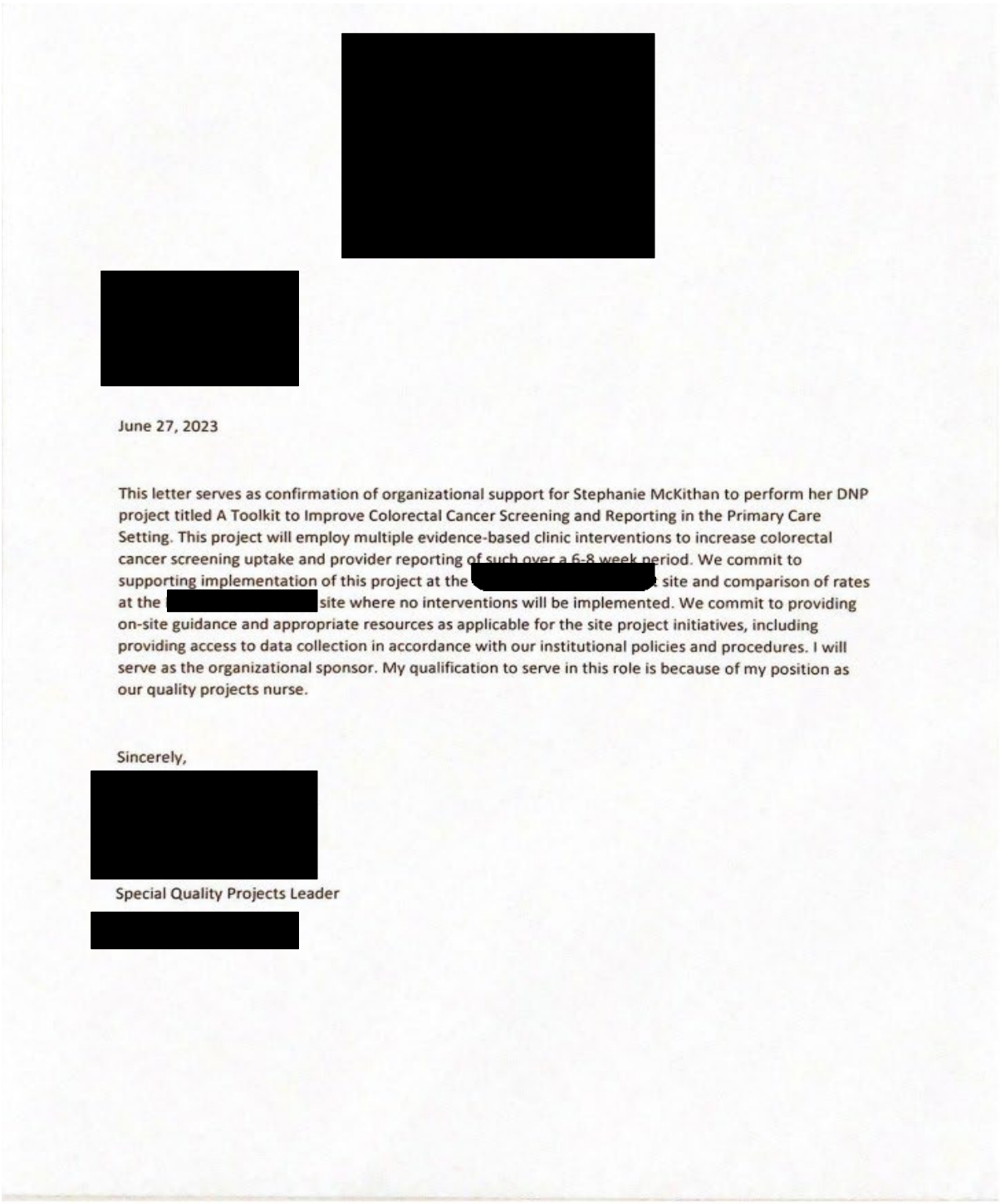
Total	0.00 USD

Total: 0.00 USD

CLOSE WINDOW ORDER MORE

(Soriano et al., 2020) https://journals.sagepub.com/doi/full/10.1177/1062860620937236

Appendix F. Organizational Support Letter



[redacted]

[redacted]

June 27, 2023

This letter serves as confirmation of organizational support for Stephanie McKithan to perform her DNP project titled A Toolkit to Improve Colorectal Cancer Screening and Reporting in the Primary Care Setting. This project will employ multiple evidence-based clinic interventions to increase colorectal cancer screening uptake and provider reporting of such over a 6-8 week period. We commit to supporting implementation of this project at the [redacted] site and comparison of rates at the [redacted] site where no interventions will be implemented. We commit to providing on-site guidance and appropriate resources as applicable for the site project initiatives, including providing access to data collection in accordance with our institutional policies and procedures. I will serve as the organizational sponsor. My qualification to serve in this role is because of my position as our quality projects nurse.

Sincerely,

[redacted]

Special Quality Projects Leader

[redacted]

Appendix G. Patient Questionnaire/ Preference Log

Colorectal Cancer Screening Questionnaire

Initials_____

1. What is your age? _____

2. Have you had either of the following Colorectal Cancer Screening tests (check all that apply):

____Colonoscopy in the past 10 years?

_____Home Stool test in the past year?

_____Cologuard in past 3 years?

_____None

3. If so, what year and what was the result (+, -, polyps, etc.)? _____

If it was a colonoscopy, WHEN did they tell you to return? _____

4. Were you or a mother, father, brother, sister, or child diagnosed with any of the following conditions before age 50 (circle all that apply): Colon or rectal cancer, abdominal radiation for cancer, ulcerative colitis, Crohn's disease, inflammatory bowel disease, familial adenomatous polyposis, or hereditary non-polyposis colorectal cancer (Lynch syndrome)? Have you had blood in the toilet or on toilet paper or change in your stool recently (diarrhea)? (Partially adapted from Soriano et al., 2021 with permission)

*****The best test is the test that you WILL do.*****

5. After reading about each type of screening test, mark which one **you** *prefer* to have when due?

__Colonoscopy Done in a clinic/repeated every 10 years if normal/May include a biopsy if polyps are found/ Requires a day of fasting with laxatives to cleanse the colon

___Home test Mailed or brought back to clinic/ Repeated yearly if normal/ Colonoscopy is performed if abnormal

___Cologuard Home test mailed to you/Mailed back to lab/ Only done every 3 years/ Colonoscopy is performed if abnormal.

English Cologuard video: https://www.youtube.com/watch?v=b1nxS_yjiEk

English FIT Test Video: https://www.youtube.com/watch?v=QANmjYtiA0Q

Spanish Cologuard Video: https://www.youtube.com/watch?v=q7ASiJCroeI

Spanish FIT Test Video: https://www.youtube.com/watch?v=pGf22a5dK34

Appendix H. Patient Questionnaire/ Preference Spanish

Cuestionario de Detección de Cáncer Colorrectal

Iniciales_____

1. ¿Cuál es tu edad? _____

2. ¿Se ha realizado alguna de las siguientes pruebas de detección de cáncer colorrectal (encierre en un círculo todas las que correspondan):

___?Colonoscopia en los últimos 10 años?

____¿Análisis de sangre en heces en el último año?

____¿(Cologuard) en los últimos 3 años?

3. ¿En qué año y cuál fue el resultado (+, -, pólipos, etc.)? _____

Si fue una colonoscopía, ¿CUÁNDO te dijeron que volvieras? _____

4. ¿Le diagnosticaron a usted o a una madre, padre, hermano, hermana o niño alguna de las siguientes condiciones? antes de los 50 años (encierre en un círculo lo que corresponda):

¿Cáncer de colon o recto, radiación abdominal por cáncer, colitis ulcerosa, enfermedad de Crohn, enfermedad inflamatoria intestinal, poliposis adenomatosa familiar (PAF) o cáncer colorrectal hereditario sin poliposis (síndrome de Lynch)? (Partial adaptation of Soriano et al., 2021 used with permission)

*****La mejor prueba es la prueba que HARÁS.*****

5. Después de leer acerca de cada tipo de prueba de detección, ¿cuál preferiría hacerse cuando le corresponda?

Colonoscopia - Realizado en una clínica/repetido cada 10 años si es normal/Puede incluir una biopsia si se encuenran polipos/ Requiere un día de ayuno con laxantes para limpiar el colon

Prueba casera - Prueba casera/ Enviada por correo o devuelta a la clínica/ Repetida anualmente si es normal/ Colonoscopía realizada si es anormal

Cologuard - Prueba casera enviada por correo/Enviada por correo al laboratorio/Repetida cada 3 años/ Colonoscopia realizada si es anormal

Vídeo Cologuard español:https://www.youtube.com/watch?v=q7ASiJCroeI

Video de prueba de FIT en español:https://www.youtube.com/watch?v=pGf22a5dK34

Appendix I. Screening Log

Colorectal Cancer Screening Log

Date Ordered	Patient Name	Telephone Number	FIT/Cologuard/ Colonoscopy (F, CG, CS)	Reminder Call Date (2 weeks)	Results (+/-)

Appendix J. Staff Education

(ACS, 2023) https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/colorectal-cancer-fact-sheet.pdf

Appendix K. Patient Education

(ACS, 2023) https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/colorectal-cancer-fact-sheet-patient-version.pdf

Appendix L. Patient Education -Spanish

Pruebas de Detección del Cáncer Colorrectal

¿Qué es el cáncer colorrectal?

El cáncer es una enfermedad en la cual las células del cuerpo se multiplican sin control. El cáncer colorrectal es un cáncer que aparece en el colon o el recto. El colon es el intestino grueso. El recto es el canal que conecta el colon con el ano.

Las pruebas de detección salvan vidas

El cáncer colorrectal es el segundo cáncer que más muertes causa en los EE. UU. entre los cánceres que afectan tanto a los hombres como a las mujeres. Pero no tiene que serlo. Las pruebas de detección del cáncer colorrectal periódicas a partir de los 45 años ¡pueden salvar vidas!

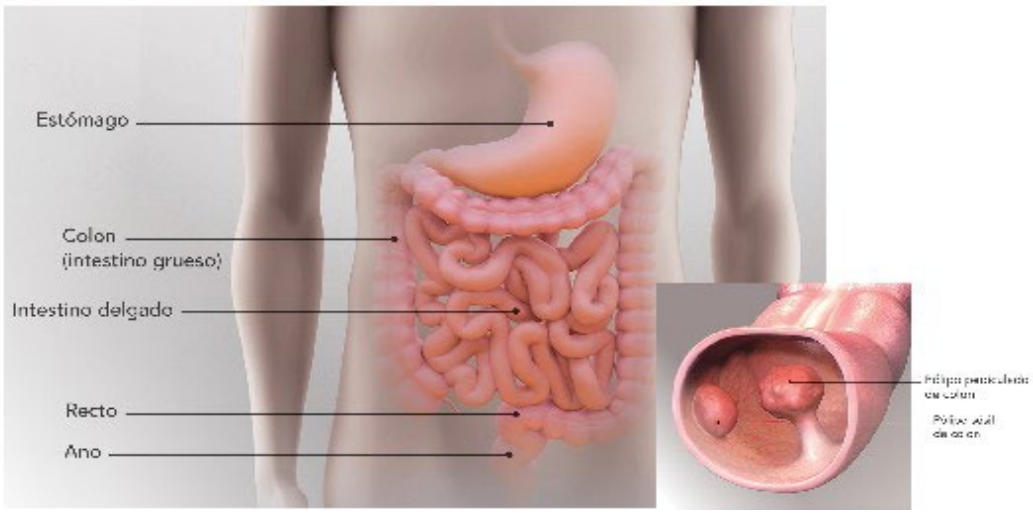
Estas son las razones:

- El cáncer colorrectal generalmente empieza a partir de pólipos precancerosos en el colon o en el recto. Un pólipo es un bulto que no debería estar ahí. Con el paso del tiempo algunos pólipos pueden convertirse en cáncer.
- Las pruebas de detección pueden encontrar los pólipos precancerosos para que se los pueda sacar antes de que se conviertan en cáncer. Las pruebas de detección también pueden encontrar temprano el cáncer colorrectal, cuando el tratamiento funciona mejor.

Usted podría estar en mayor riesgo si:

- Usted o un familiar cercano han tenido pólipos colorrectales o cáncer colorrectal.
- Tiene enfermedad inflamatoria intestinal, enfermedad de Crohn o colitis ulcerosa.
- Tiene algún síndrome de origen genético, como poliposis adenomatosa familiar (PAF) o cáncer colorrectal hereditario sin poliposis (síndrome de Lynch).

Las personas con mayor riesgo de tener cáncer colorrectal posiblemente necesiten comenzar con las pruebas antes o hacérselas con mayor frecuencia que otras personas. Si usted cree que podría estar en mayor riesgo, hable con su proveedor de atención médica sobre las pruebas de detección de rutina que sean adecuadas para usted.



(CDC, 2023) Developed by the CDC and used under public domain. Use does not constitute its endorsement or recommendation by the Centers for Disease Control and Prevention.

Appendix M. Staff Education Pre and Post Test

Staff Education Pre and Post Test

Multiple choice on Survey Monkey

Link: https://www.surveymonkey.com/r/ZZTC2VH

What is the frequency (in years) recommended if results are normal for:

_____Colonoscopies _____FIT or FOBT tests _____Cologuard

If a home test is abnormal what should occur immediately?

_____

In 2018, what age did the ACS recommended for initiation of screening in average risk patients?

_____

What conditions require screening earlier than this?

_____

Which test is considered the 'gold standard' for CRCS?

_____

Which ethnic group has higher incidence and poorer outcomes of CRC?

_____

Why does screening for CRC save lives?

_____

Name 2 modifiable risk factors for CRC:

_____ _____

How many eligible patients at the FQHC are not documented as being up to date on screening?

_____

Which tests does the FQHC recommend for use in typical patients of average risk?

_____

Appendix N. Staff Education Plan

Staff Education Plan

Explanation and Consent

Review the nurse practitioner CRCS education by ACS (Appendix I)

Watch the instructional videos.

Know how to order Cologuard in the portal for resulting back into the EHR.

Remind Patients to date BOTH the card and the order form on the FIT test (put a flag on them)

“Freshness counts”

“Keep kit in bathroom.”

“Poop on demand” in the office helps potential FIT non-compliance, encourage if possible.

Know where to document in Cloud Craft to give patient credit and scan results as evidence to get organizational credit - Notes don’t flow into analytics correctly (Review)

CRCS Log to keep up with outstanding screens and close the ‘loop’ (Appendix I)

Shared decision - when patient thinks they made decision, they are more likely to complete the process.

“The best test is the one that gets done.”

Posters for exam and waiting room.

Timely reminder in 2 weeks call to nudge to completion.

Timely referral to GI for abnormal FITs/ Cologuards

Remind of allocation- incentive to do Cologuard this year**

Review information for all pre / post-test questions.

Review the patient flow for the initiative outlining each teammate’s part.

Nurse practitioner education: Personal screening rate vs organizational rate and goal rate

Appendix O. Staff Consent to Participate in Study

Consent to Participate in an Educational Study

Title of the Project: Implementation of a Toolkit to Improve Colorectal Cancer Screening Rates

Principal Investigator: Stephanie McKithan/ Doctoral Candidate/ School of Nursing/ Liberty University

Invitation to be Part of a Research Study

You are invited to participate in a research study. To participate, you must be a staff member of the Medical Center and at least 18 years of age. Taking part in this research project is voluntary.
Please take time to read this entire form and ask questions before deciding whether to take part in this research.

Wha is the study about and why is it being done?

The purpose of the study is to evaluate the success of an educational luncheon about colorectal cancer screening by testing your knowledge before and after.

Wha will happen if you take part in this study?

If you agree to be in this study, I will ask you to do the following:

1. Take a pre-test on Survey Monkey which will test your knowledge of colorectal cancer and screening. Results will come to the principal researcher and will be anonymous. It will take approximately 3 minutes to complete.
2. Participate in an educational in-service that will discuss colorectal cancer, screening, and the intervention that is planned at your facility. This will take approximately 30 minutes.
3. Repeat the test on Survey Monkey which will test your knowledge and the effectiveness of the in-service. This will also take approximately 3 minutes to complete.
4. After completion of the study period (6-8 weeks), you will receive a post implementation staff survey on Survey Monkey which you will be asked to complete anonymously to inform the principal researcher of what you believe did and did not work during implementation of the trial. This will take approximately 5 minutes to complete.

Hov could you or others benefit from this study?

Participants should expect to receive lunch and an increased understanding of colorectal cancer, screening, and the screening initiative by taking part in this study.
Benefits to society may include an increase in colorectal cancer understanding to patients of this clinic through you and increased uptake of colorectal cancer screening rates which may identify malignancies early and increase survival rates. Benefits to your organization may include improved colorectal screening rates which could result in continued or increased resources. The results of the study may also provide a path for other clinics that need assistance meeting clinical quality measures.

What risks might you experience from being in this study?

The expected risks from participating in this study are minimal, which means they are equal to the risks you would encounter in everyday life.

How will personal information be protected?

Participant responses will be anonymous. The principal researcher will not be able to link individual responses to specific participants associated with the data.

How will you be compensated for being part of the study?

Participants will not be compensated for participating in this study but will receive lunch for attending the educational in-service.

Is study participation voluntary?

Participation in this study is voluntary. Your decision whether to participate will not affect your current or future relations with Liberty University or the Medical Center. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

What should you do if you decide to withdraw from the study?

If you choose to withdraw from the study, please exit the survey and close your browser. Your responses will not be recorded or included in the study.

Whom do you contact if you have questions or concerns about the study?

The researcher conducting this study is Stephanie McKithan. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact her at [redacted]. You may also contact the researcher's faculty sponsor, Dr. Sherri Walker, at [redacted].

Whom do you contact if you have questions about your rights as a research participant?

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher, **you are encouraged** to contact the IRB. Our physical address is Institutional Review Board, 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA, 24515; our phone number is 434-592-5530, and our email address is irb@liberty.edu.

Disclaimer: The Institutional Review Board (IRB) is tasked with ensuring that human subjects research will be conducted in an ethical manner as defined and required by federal regulations. The topics covered and viewpoints expressed or alluded to by student and faculty researchers are those of the researchers and do not necessarily reflect the official policies or positions of Liberty University.

Your Consent

Before agreeing to be part of the research, please be sure that you understand what the study is about. You can print a copy of the document for your records. If you have any questions about the study later, you can contact the principal researcher using the information provided above.

I have read and understood the above information. I have asked questions and have received answers. I consent to participate in the study.

_____

Printed Subject Name

_____

Signature & Date

Appendix P. Post-Implementation Survey

Post Implementation Survey

Multiple choice on Survey Monkey

Link: https://www.surveymonkey.com/r/X9BK8N2

Was the toolkit simple to use?

Were the interventions feasible to deliver in your clinic?

Did the patients accept the program?

Which tools in the toolkit do you think were most beneficial for getting patients screened?

What tools in the toolkit need elimination or modification?

What tools in the toolkit were most often skipped/ forgotten?

Did this toolkit help your clinic meet the objectives for screening?

Will you continue using some or all aspects of the toolkit?

Do you think this toolkit should be implemented in other clinics?

Appendix Q. Data Collection Sheet

	Pilot Clinic	**Cohort Control Clinic**
Pre-Intervention		
Eligible	184	178
Screened	62	44
Percent/Rate	34%	25%
Post Intervention		
Eligible	238	200
Screened	95	44
Percent/Rate	40%	22%

Data Collection Form

Clinic Screening Data Table

Aggregate	Pre-Test Mean Score	Post-Test Mean Score
Staff CRC Knowledge	54% correct answers	96.6% correct answers

Educational Effectiveness Data Table

	Pre-Interventional Rate	Post-Interventional Rate
NC CRC Screening Benchmark	35%	35%
Pilot Screening Average	34	40
Cohort Screening Average	25	22

Adherence to Clinical Guidelines Data Table

Appendix R. Screening Measure Analysis

Pretrial Period Counts	Pilot	Cohort
Eligible Patients	184	178
Patients Accepting Screening	62	44
Patients Declining Screening	122	134

Pretrial Period Percentages	Pilot	Cohort
Eligible Patients	100%	100%
Patients Accepting Screening	34%	25%
Patients Declining Screening	66%	75%

Trial Period Counts - Actual	Pilot	Cohort
Eligible Patients	238	200
Patients Accepting Screening	95	44
Patients Declining Screening	143	156

Trial Period Percentages - Actual		
Eligible Patients	100%	100%
Patients Accepting Screening	40%	22%
Patients Declining Screening	60%	78%

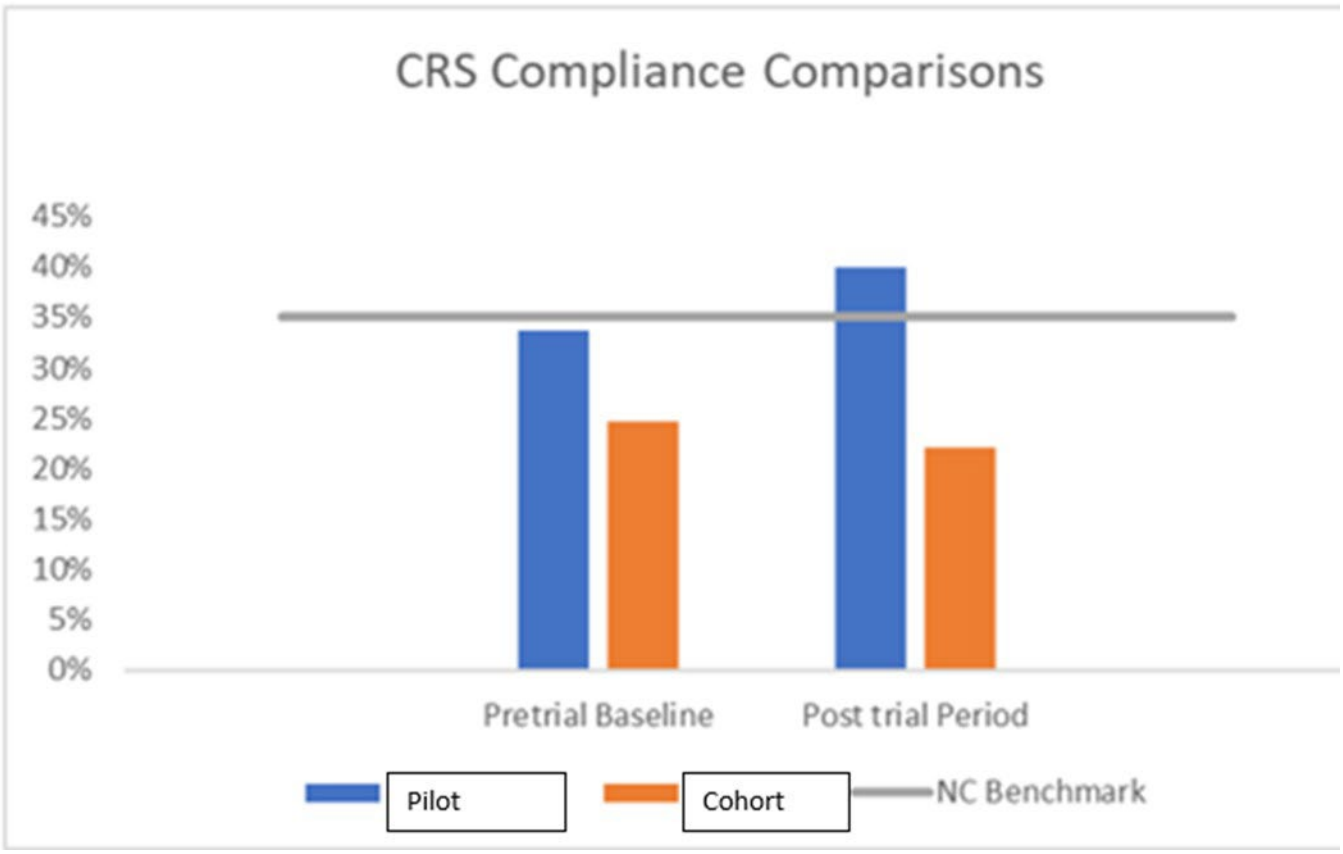
To check the null hypothesis, calculate the expected values from the trial period using the number of eligible patients in the trial period and the percentages. Then test the hypothesis using the chi square statistic

Trial Period Expected Counts	Pilot	Cohort
Eligible Patients	238	200
Patients Accepting Screening	80	49
Patients Declining Screening	158	151

Chi Square Statistic	4.12	0.79
Probability of this Chi Square Value	4.2%	37.3%
Reject the null hypothesis	Yes	No

Appendix S. Benchmark Measure Analysis

Comparison with Statewide Benchmarks



Appendix T. Staff Education Measure Analysis

Null Hypothesis: Implementation of the training will not affect staff knowledge
Alt Hypothesis: Implementation of the training will positively affect staff knowledge

The Data:

Survey Data	Pre	Post	Expected if No Impact
Number of Participants	5	3	
Number of Survey Questions	10	10	
Possible Correct Answer	50	30	
Actual Correct Answers	27	29	16
Actual incorrect Answers	23	1	14
Chi Square Value		22	
Probability of this Chi Square Value		0%	

Reject the null hypothesis Yes

Appendix U. IRB Approval Letter

LIBERTY UNIVERSITY.
INSTITUTIONAL REVIEW BOARD

August 16, 2023

Stephanie McKithan
Sherri Walker

Re: IRB Application - IRB-FY23-24-259 Implementation of a Tool Kit to Improve Colorectal Cancer Screening Rates

Dear Stephanie McKithan and Sherri Walker,

The Liberty University Institutional Review Board (IRB) has reviewed your application in accordance with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulations and finds that your study does not meet the definition of human subjects research. This means you may begin your project with the data safeguarding methods mentioned in your IRB application.

Decision: No Human Subjects Research

Explanation: Your project is not considered human subjects research because evidence-based practice projects are considered quality improvement activities, which are not "designed to develop or contribute to generalizable knowledge" according to 45 CFR 46.102(l).

Please note that this decision only applies to your current application. Any modifications to your protocol must be reported to the Liberty University IRB for verification of continued non-human subjects research status. You may report these changes by completing a modification submission through your Cayuse IRB account.

For a PDF of your IRB letter, click on your study number in the My Studies card on your Cayuse dashboard. Next, click the Submissions bar beside the Study Details bar on the Study Details page. Finally, click Initial under Submission Type and choose the Letters tab toward the bottom of the Submission Details page.

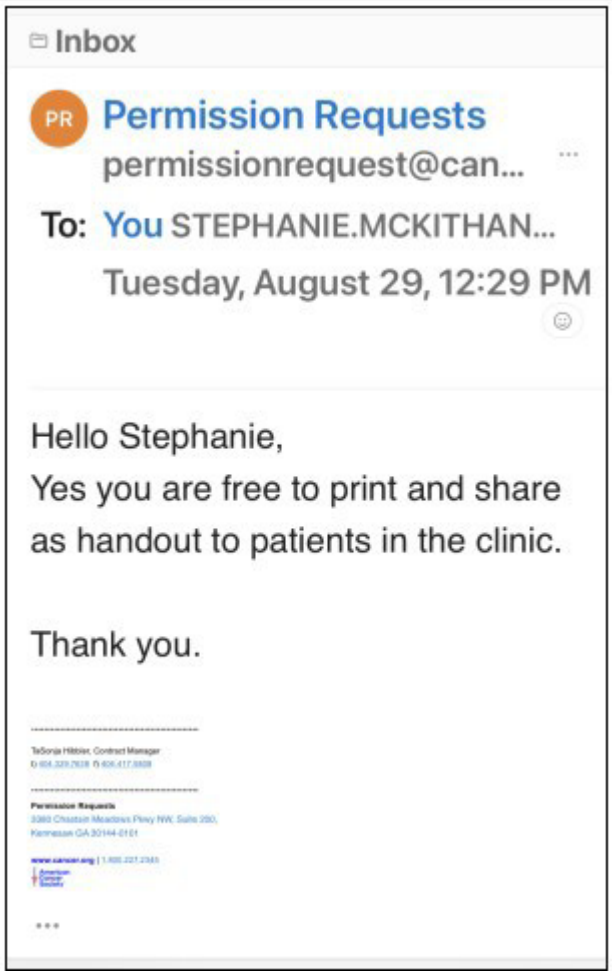
Also, although you are welcome to use our recruitment and consent templates, you are not required to do so. **If you choose to use our documents, please replace the word *research* with the word *project* throughout both documents.**

If you have any questions about this determination or need assistance in determining whether possible modifications to your protocol would change your application's status, please email us at irb@liberty.edu.

Sincerely,

G. Michele Baker, PhD, CIP
Administrative Chair
Research Ethics Office

Appendix V. American Cancer Society Permission Statement


Inbox

PR Permission Requests
permissionrequest@can...

To: You STEPHANIE.MCKITHAN...
Tuesday, August 29, 12:29 PM

Hello Stephanie,
Yes you are free to print and share as handout to patients in the clinic.

Thank you.