Increasing Fecal Immunochemical Testing in a Community Health Clinic

LaToya White

Under Supervision of

Marilyn Miller

University of Maryland School of Nursing

Second Reviewer

Barbara Van de Castle

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Author's Note

The author acknowleges a possible conflict of interest as this scholarly project was carried out at the current employment place. Correspondence concerning this manuscript should be addressed to LaToya White, University of Maryland School of Nursing. Email: latoya.white@umaryland.edu.

Abstract

Problem and Purpose: In 2022, data collected from the electronic health records at a community health center showed that only 24.87% (n=226) out of 908 patients were considered current for colorectal cancer screening. Of those patients who were current, 177 fecal immunochemical test (FIT) kits were ordered by staff, and 35% completed. Several causes of failure to screen include inadequate follow-up after FIT orders, failure to utilize lab tracking reports to monitor pending labs due to staff shortages, and non-adherence to clinic procedures for distributing FIT kits to patients. The purpose of this quality improvement project was to implement and evaluate the effectiveness of a multi-component process for improving colorectal screening by increasing FIT screening by 25% through increased utilization of FIT testing.

Methods: The initiative occurred between September through December 2023. Metrics measured the overall percentage of FIT ordered; reminder calls made, FIT completed and result follow-up. The process included maintaining an adequate supply of FIT kits and the generation of a report listing the patients eligible for Colorectal Cancer Screening (CRCS) each clinic day, which also prompted mailing of FIT kits to patients seen virtually who opted for FIT. A reminder telephone call was made to patients who had not returned the completed test after one week.

Results and Conclusion: During the fourteen weeks FIT was ordered for 117 eligible patients with a 54% completion rate (n=63). Staff followed up results with 100% of eligible patients (n=63). Reminder phone calls were attempted for 79% of patients that had not returned FIT after 1 week (n=93) and completed for 52% of the patients (n=61). Data suggests that a multi-component process including distribution of FIT kits, reminder phone calls and provider follow-up may increase FIT screening and patient participation in colorectal cancer screening.

Keywords: FIT, phone reminders, occult blood, stool testing, colorectal cancer screening

Increasing Fecal Immunochemical Testing in a Community Health Clinic

According to the American Cancer Society, colorectal cancer is the second most common cancer in the United States (ACS, 2021). Colorectal cancer screening (CRCS) is recommended by the US Preventive Task Force (USPTF) for ages 45-74 as a preventive measure to reduce morbidity and mortality which now aligns with ACS (2021). Despite the recommendations screening rates were low at a community health care center serving patients with diverse health care needs, including cancer screening services for adult patients. Data collected from the electronic health records database showed that only 24.87% out of 908 patients between the age of 45-75 that had a medical visit in the last 12 months, were considered current with a colorectal cancer screening requirement. A root cause analysis (Figure 1) identified several causes of inadequate screening rates including a) time restraints at primary care provider (PCP) visits, b) poor follow-up after fecal immunochemical test (FIT) were ordered c) non-use of lab tracking report to follow up on outstanding labs due to staff shortages, and d) non-compliance with clinic procedures for distribution of FIT kits to patients.

The purpose of this quality improvement project was to enhance CRCS efforts by increasing FIT screening at a community health organization. The goal was to increase FIT screening by 25% by implementing a CRCS multi-component process in the primary care settingover 15 weeks. intervention.Colorectal cancer is common and the strategic goal of the facility is to enhance preventive health within the community, improve early diagnosis and treat colorectal cancer through multicomponent intervention.

Available Knowledge

Studies demonstrate strong evidence in support of multicomponent interventions to increase CRCS. A systematic review by Issaka et al. (2019) showed that multilevel interventions that include administration of FIT kits accelerate improvements in CRCS rates. Coronado et al. (2019) found that clinics with FIT kits had significantly higher adjusted clinic-level CRCS than those without. The systematic review involved 41,193 participants aged 50 to 74 years in 26 federally qualified health center clinics, with the inclusion criteria being patients who were due for CRC screening with no Electronic Health Record (EHR) evidence of completing a fecal test during the past 11 months. A randomized controlled trial (Rhode et al., 2018) found that a health department-based mailed FIT program targeting Medicaid beneficiaries was feasible and resulted in greater screening completion than a reminder letter alone. The study involved 2,144 Medicaid. beneficiaries at average CRC risk and no evidence of screening using Medicaid claims data.

Dougherty et al. (2018) found Fecal Occult Blood Test outreach and patient navigation, especially multi-component interventions, showed increased CRCS rates in US trials. Based on the review of evidence the use of FIT kits has had a positive impact on increasing the rate of completed CRCS and supports this intervention as a quality improvement initiative (Coronado et al., 2018; Brenner et al., 2018; Rawls et al., 2021; Dougherty et al., 2018). A review of the evidence is presented in the evidence review table (Table 1) and a synthesis is presented in the evidence synthesis table (Table 2).

Rationale

The project was supported by the Complex Innovations Framework (Figure 2) to determine the effectiveness of having FIT kits readily available, mailing the kits to patients who were seen virtually and providing patient reminders to improve colorectal screening in a community health clinic. The quality improvement project was aimed at safety, efficiency, patient-centeredness, timeliness, effectiveness, and equity. The framework proposed by Helfrich et al. (2007) consists of six main domains: the innovation itself, the organization implementing the innovation, the individuals involved in implementation, the implementation process, the outer context in which implementation takes place, and the outcomes of implementation. The innovation concepts supports the project's idea of implementing and evaluating the efficiency of a multi-component process for improving colorectal screening in a community health clinic through increased utilization of FIT. The individuals involved in the implementation include patients, healthcare providers and medical assistants. The implemtation process includes giving FIT to patients and the patients return the FIT for reporting.

Overall, the framework proposed by Helfrich et al. (2007) provides a useful tool for understanding the multiple factors that influence implementation effectiveness for complex innovations. By considering each of the domains and subdomains identified in the framework, the healthcare center developed a more comprehensive approach to implementation planning and addressed any potential barriers to successful implementation of the project.

Methods

Context

Prior to project implementation the need for increased colorectal cancer screening (CRCS) was recognized through internal clinical quality improvement analysis using the Quality Performance Dashboard. The work flow included screening eligible patients and the nursing administrative staff preparing daily huddle sheets. The providers would then review NexGen Care guidelines and chart alerts during patient appointments and place orders for screening. The requisition was given to the patient and they received FIT instructions and the kit from the lab. The FIT kits were returned and results reported.(see Figure 3).

The project was in a community health clinic serving a diverse population. The clinic is equipped with an Electronic Health Record (EHR) system and employs lab technicians, medical assistants, providers, and administrative staff. The community center embraced virtual visits as part of its healthcare delivery model.

The target population included patients eligible for colorectal cancer screening (CRCS) at the community health clinic. This population is diverse in demographics, reflecting the community the clinic serves. The patients had varying levels of health literacy, cultural backgrounds, and access to healthcare resources. The clinic operates within a culture that values quality improvement and patient care. The leadership is described as strong and visionary, indicating a commitment to positive change. The community served by the clinic had its cultural nuances such as language barriers, health literacy, and religious beliefs that needs to be considered when delivering healthcare. The clinic faced challenges such as staff shortages, particularly in the context of absences, and time constraints affecting consistent colorectal screening practices.

Intervention

In the planning stage phase, a survey (see Appendix A) was given to the staff members (providers and medical assistants) to guide a refresher education session regarding FIT. Attendance was recorded using a QR code into REDCap, a secure, HIPAA compliant, password protected server with dual authentication (Appendix B Attendance sheet). After getting the responses from the staff, the PL customized a refresher session based on the answers. During implementation, 10 FIT kits were stocked weekly (based on a weekly average of 20 patients due for colorectal screening) by medical assistants in each of the three employee pods to promote availability and ready distribution.

Having FIT kits available allowed staff to provide education based on test kit instructions on how to complete the test kit, enhancing patients' comprehension. The office manager printed out a daily report including patients eligible for CRCS for the day or days later if there was a planned absence to give to medical assistants and providers. Medical assistants (MA) screened all eligible patients to see if they were willing to complete a FIT. Certified MAs ordered a FIT if the patient was found eligible. If the medical assistant was not certified, then the provider inputed the order.

For patients seen in the clinic, the medical assistant handed out FIT kits. When FIT was ordered, the MA printed a requisition and label, highlighted the collection date, and placed the label on the FIT kit and requestion in the FIT envelope. The MA then provided the FIT to the patient and reviewed instructions for use and how to return the FIT kit to a lab in person or by mail (the kit has the United States Postal Service prepaid postage). If patients dropped the kit off at the clinic, they gave it to the front desk staff. For patients seen virtually, when medical assistants or providers initiated the call, they screened the patient by asking which method of CRC screening they preferred.

If FIT was selected, the medical assistant placed the FIT test kit and requisition in a manila envelope and placed the envelope in the bin for pickup to the Administration Building by the end of the day, where it was mailed to the patient the next day. After one week of the order date, the reminder process was initiated via telephone by the current staff CHW or RN for those who had not yet returned the test (See Figure 4). Redcap is a secure web application for building and managing online surveys and databases. If a patient misplaced a FIT, then the medical assistant sent one to them in the mail. After processing, FIT results were automatically uploaded to the EHR and sent to the provider inbox.

The provider contacted patients with results and referred them for further testing if abnormal. If they had not returned the kit in one week, the patient received a phone call from the

CHW or RN. Strategies and tactics to achieve the project aim included providing daily reports, obtaining feedback from staff at meetings, and conducting chart audits. To ensure inclusion, all eligible patients were included in the screening process, whether seen in person or virtually.

Measures

The first project goal was to introduce the staff (MA and providers) to the new process of ordering, mailing, and completing FIT through a refresher session by September 4 th 2023. The project lead conducted the colorectal screening survey (Appendix A) before and after refresher session. Attendance for the refresher sessions was recorded on the colorectal refresher course attendance survey (Appendix B). The Chart audit (Appendix C) was used to collect data on the percentage of completed FITs and phone calls attempted and completed. The numerator included the total number of patients aged 45 to 75 who completed a FIT, while the denominator encompassed the total number of patients aged 45 to 75 who were ordered for a FIT. See Table 3(measurement plan) for the measurement plan. A consistent system of obtaining data was ensured by using electronic health records for chart audits, defined CRC screening parameters, and entering all data into REDCap (Research Electronic Data Capture).

Ethics

A non-human subjects research determination was obtained from the University of Maryland School of Medicine (UMSOM) Institutional Review Board (IRB) The site did not have its own IRB and accepted the determination from the UMSOM. To ensure privacy, all data was collected in a private location. Confidentiality was maintained by entering data directly in REDCap, a secure, HIPAA compliant, protected server with dual authentication. All data was de-identified prior to the generation of any reports. Only the project lead and faculty advisor had access to the data. The project lead was compliant with CITI and HIPAA certifications. The project lead was an employee at the organization which posed a potential conflict of interest. The risk for bias was minimized by conducting the project under supervision of the facility's leadership.

Results

The quality improvement project aimed to address the low colorectal cancer screening (CRCS) rates identified in the community health center by implementing a multi-component intervention focused on increasing FIT screening utilization by 25%. Prior to implementation and after education, staff completed the Colorectal Screening Survey (Appendix A) to assess colorectal screening ordering practices. The results of the survey were used to tailor education. One hundred percent of the staff attested to completion of the education (Colorectal Refresher Course Attendance, Appendix B). The first process goal was that by December 11th, 2023, 100% of medical assistants and providers order FIT for all eligible patients. Of 117 eligible patients, 117 were ordered a FIT kit. The second process goal was that by December 11th, 2023, 100% of patients with a FIT kit by mail or in person would receive a phone call one week later to remind them to return the kit. A reminder phone call was attempted for 79% of patients that had not returned FIT after one week (n=93) and completed for 52% of the patients (n=61). The results are depicted in the run chart Phone Call Reminders (Figure 5). There were no runs, shifts, or trends. Astronomical data points were noted when FIT was returned prior to the reminder call and during staff absences. The results show that staff followed up results with 100% of eligible patients (n=63). The first outcome goal was that by December 11th, 2023, 100% of patients with FIT returned will have results followed-up by staff. Of 117 patients eligible for FIT screening, 63 (54%) all received staff follow-up (Follow-up for Completed FIT Results (Figure 6). The second outcome goal was that by Dec 11th, 2023, the community clinic will increase FIT completion by

25%to 50% (for ages 45-75). Data analysis revealed a 54% completion rate for FIT testing, exceeding the initial goal of a 25% increase compared to 38% completion rate during the same time frame in 2022. The data was analyzed by comparing the number of FIT completed divided by the number of FIT ordered. There were three runs, no shifts, no trends. Astronomical data points were noted with staff absence and when colorectal cancer eligibility sheets were not passed out to providers to alert them to order FIT.

The organization observed a notable increase in FIT screening rates by implementing the multi-component intervention, including the distribution of FIT kits, reminder phone calls, and provider follow-up. This change demonstrates a positive shift in the organization's approach to CRCS, aligning with the project's purpose of improving screening rates. The observed associations among interventions (tactics) and outcomes highlight the effectiveness of the multi-component approach in achieving the project's goals. Specifically, the distribution of FIT kits ensured accessibility to screening for eligible patients, while reminder phone calls were a proactive measure to encourage test completion. Provider follow-up further facilitated result interpretation and appropriate follow-up actions, contributing to the overall increase in FIT screening rates.

Relevant contextual elements, such as staff shortages and clinic procedures for FIT kit distribution, influenced the implementation and effectiveness of the interventions. Despite these challenges, the organization successfully adapted its processes to overcome barriers and achieve the desired outcomes. The effectiveness of early colorectal cancer (CRC) detection relies on a well-established monitoring system for FIT tests. In this project, the median time it took patients to submit their FIT was two weeks. The run chart for the percentage of weekly phone call reminders (Figure 5) demonstrated fewer calls some weeks when FIT kits were returned before the reminder call was due. This is a positive outcome, and there is no need to modify the interventions. The project's limitation is that the 15-week duration might not be long enough to fully demonstrate the intervention's impact, considering the typical delay in returning FIT kits. Future projects are needed to investigate how long it took for the provider to follow up on patients given the FIT.

Discussion

The key findings of the quality improvement project include an increase in FIT screening rates, with a completion rate of 54% observed. This improvement positively impacts both individuals and the healthcare system, as increased screening rates lead to earlier detection of colorectal cancer and improved patient outcomes. The follow-up for completed FIT results indicate that 117 participants were eligible for FIT screening. The number of compled FIT screening was 63 and all 63 were followed up by staff. The sustainability plan includes integrating the multi-component intervention into routine clinic procedures, ongoing staff training, and monitoring of screening rates to ensure continued success.

The project's results align with other publications evaluating multi-component interventions to increase colorectal cancer screening rates. Studies by Issaka et al. (2019), Coronado et al. (2019), Rhode et al. (2018), and Dougherty et al. (2018) have consistently demonstrated the effectiveness of similar interventions in improving screening rates. The observed completion rate of 54% falls within the range of completion rates reported in the literature, further supporting the validity of the project's findings. While the project achieved its primary goal of increasing FIT screening rates, some differences between observed and anticipated outcomes were noted. Factors such as staff shortages and challenges in maintaining adequate follow-up procedures may have contributed to lower-than-expected completion rates.

Additionally, variations in patient demographics and preferences may have influenced the participation in the screening program.

Several factors may have limited the internal validity of the project, including some data not being captured due to mislabeling of FIT kits and documentation errors. Further evaluation of clinic processes need to be conducted to minimize this source of error. Efforts were made to minimize these limitations by implementing standardized FIT kit distribution, reminder phone calls, and data collection procedures. Staff training and ongoing monitoring of screening rates helped ensure consistency and accuracy in data collection and analysis.

Conclusion

In summary, this quality improvement project successfully increased FIT screening rates and demonstrated positive impacts on individuals and the healthcare system. The project's results align with findings from other publications, highlighting the effectiveness of multicomponent interventions in improving colorectal cancer screening rates and informing future efforts to promote preventive healthcare initiatives. By increasing FIT screening rates, the project contributes to early detection and prevention of colorectal cancer, ultimately improving patient outcomes and reducing healthcare costs associated with advanced disease stages. Additionally, the project addresses critical gaps in colorectal cancer screening practices within the community health center, enhancing the overall quality and safety of care delivery. The multi-component intervention's likelihood of sustainability is high due to its integration into routine clinic procedures and ongoing staff training efforts. This project may be used as a model to develop a comprehensive plan to improve colorectal cancer screening outcomes in similar sites. Future QI initiatives should prioritize collaborative approaches, staff training, and sustainability planning to maximize impact and improve healthcare delivery, quality, safety, and patient outcomes.

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Table 1

Literature Evidence Review

Issaka, R. B., Avila, P., Whitaker, E., Bent, S., & Somsouk, M. (2019). Population health interventions to improve colorectal cancer screening by fecal immunochemical tests: A systematic review. *Preventive medicine*, *118*, 113-121.				**Level and Quality** **Level – II** -Systematic review of 20 RCTs and 1 quasi-experimental study. Only one study was observational. **Quality B**- The results were fairly consistent and generalizable. The sample size for the study was also sufficient given the number of studies reviewed; results reached led to a fairly definitive conclusion	
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
The study evaluates whether multimodal FIT intervention could help CRC screening	Systematic review of RCTs,1 quasi-experimental and 1 observational study	**Sampling Technique:** The sampling technique used the methodology described in the Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards **Participants:** randomized clinical trials (RCTs), quasi-experimental, and observational study on patients under CRC screening using the fecal immunochemical tests (FIT). **Setting**; Clinical **Excluded:** **1149** Full-text studies excluded 19**9** Duplicate records **855** lack of evidence, **28 –** Outcome out of scope, **19-** FOBT screening**, 8-** Pilot studies, **13 –** Descriptive studies**, 10 -** Abstract only, **8** – Review Studys, 4 -Method Papers, 4-survey studies, 3- incomplete data, 2-simulated studies, 1-population out of scope. **Accepted:** 23 RCTs, 1 quasi-experimental and 1 observational study	**Control:** Baseline interview on CRC screening guidelines, subjects who received just printed material for screening, education session with providers **Intervention Protocol:** The intervention protocol involved the use of Mailed FIT outreach and pre- and post-FIT reminders **Treatment Fidelity**: Two authors (RBI and PA) independently assessed the methodologic quality of each study included in the systematic review using a tool developed by the Cochrane Collaboration for randomized and nonrandomized controlled trials. All studies were rated in terms of bias risk from high to low, with high-risk studies eliminated	**Dependent Variable:** Rate of CRC screening **DV Measure:** The number of people who complete CRC screening	**Statistical Results:** Mailed FIT outreach consistently increases CRC screening rates, but magnitude varies. Pre- and post-FIT reminders lead to small increases in screening completion. **Conclusion:** Multilevel interventions may accelerate improvements in CRC screening rates.

Coronado, G. D., Petrik, A. F., Vollmer, W. M., Taplin, S. H., Keast, E. M., Fields, S., & Green, B. B. (2018). Effectiveness of a mailed colorectal cancer screening outreach program in community health clinics: The STOP CRC cluster randomized clinical trial. *JAMA Internal Medicine, 178*(9), 1174– 1181. https://doi.org/10.1001/j amainternmed.2018.362 9	**Level and Quality** **Level: 1** – Research is an RCT **Grade A** – over 40,000 heterogenous sample population with trustworthy and conclusive findings.

Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
To determine whether a multifaceted intervention increases adherence to annual FOBT compared with usual care	Randomized Controlled Trial	**Sampling Technique:** clustered random sampling technique (convenience) **Eligible Participants:** 41,193 participants aged 50 to 74 years in 26 federally qualified health center clinics. The patients needed to have had a clinic visit during the 12 months prior to accrual, and were due for CRC screening with no EHR evidence of completing a fecal test during the past 11 months, flexible sigmoidoscopy during the past 4 years, or colonoscopy during the past 9 years; no evidence of an order for a fecal test in the past 6 months or a referral for a sigmoidoscopy or colonoscopy in the past year **Setting:** 26 federally qualified health center clinics **Excluded:** adults with evidence of relevant health conditions (eg, colorectal cancer, colon disease, end-stage renal failure). **Accepted:** 21134 individuals in intervention clinics and 20059 individuals in usual care clinics over the accrual interval. **Intervention:** customized EHR-embedded tools, training in the use of these tools, a collaborative environment for continued learning after initial training, and a standardized practice improvement process. **Power analysis/Achieved:** The authors specified clinic as a clustering variable to account for intra-clinic correlation; the intraclass correlation coefficient was 0.05 after covariable adjustment. All analyses were 2-tailed and considered significant if $P \leq .05$	**Control protocol:** Usual process for CRC screening **Intervention Protocol:** 181 intervention comparisons in 366,766 patients **Treatment Fidelity:** The researchers used generalized estimating equations (GEE) with a logistic link to model the patient-level data. They weighted patient data so that each clinic's data had an equal weight. The models were adjusted for age, sex, and health center. They used robust variance estimators and independent correlation structures, including individual clinics as a clustering variable to account for intra-clinic correlation	**Dependent Variable:** clinic-level proportions of adults who completed FIT secondary outcome was adults who had completed colorectal cancer screening **DV Measure** The number of eligible patients who completed the FIT within 12 months post intervention	Compared with usual care clinics, intervention clinics had significantly higher adjusted clinic-level proportion of participants who completed a FIT (13.9% vs 10.4%; difference, 3.4 percentage points; 95% CI, 0.1%-6.8%) and any colorectal cancer screening (18.3% vs 14.5%; difference, 3.8 percentage points; 95% CI, 0.6%-7.0%)

Mehta, S. J., Induru, V., Santos, D., Reitz, C., McAuliffe, T., Orellana, C., Volpp, K. G., Asch, D. A., & Doubeni, C. A. (2019). Effect of Sequential or Active Choice for Colorectal Cancer Screening Outreach: A Randomized Clinical Trial. *JAMA Network Open*, *2*(8), e1910305. https://doi.org/10.1001/jamanetworkopen.2019.10305	**Level and Quality Level 1,** since the research was an RCT **Grade A** basing on the sample size and level of generalizability and consistency of results.

Purpose or Hypothesis	Type of Evidence and Research Design	Sample (population, size, setting)	Intervention Procedures	Primary Outcome/Measures	Results Conclusions
The study compares sequential (fecal immunochemical test) navigation and patient reminders in improving colorecta cancer screening	Randomized controlled trial	**Sampling Technique:** Random sampling **Participants:** The participants included patients aged 50 to 74 years with at least 2 primary care visits in the 2-year pre-enrollment period if they were eligible but not up to date on CRC screening. **Setting:** Academic health system **Excluded:** Patents below 50 years and those who were up to date with their CRC screening **Accepted:** 438 patients. **Control:** 146 assigned to colonoscopy only **Intervention:** 146 assigned to sequential choice, 146 assigned to active choice **Power analysis:** The study was conducted using a 2-sided $\chi 2$ test with 80% power and a type I error rate of 0.025, accounting for 3 pairwise comparisons with Bonferroni correction (P value of .05 / 2 = .025)	**Control Protocol:** assigned to colonoscopy only **Intervention Protocol:** Eligible patients were randomized in 1:1:1 ratio using a computerized random number generator. All patients got a letter from their primary care clinician indicating their screening was overdue and the benefits of CRC screening. Colonoscopy-only arm received a phone number to call for direct scheduling of colonoscopy through the call center. Those in the sequential choice arm received a phone number to call for direct scheduling of colonoscopy. Those in the active choice arm received a phone number to call for direct scheduling of colonoscopy and an enclosed FIT kit. . **Treatment/Fidelity:** Eligible patients received mailed outreach about CRC screening. Eligible patients were randomly assigned using equal ratios to 3 outreach groups Patients were reached out using direct phone call for scheduling colonoscopy and a mailed FIT kit if there was no response within 4 weeks.	**DV:** The primary outcome was CRC screening completion (FIT or colonoscopy) within 4 months of initial outreach. The secondary outcomes were CRC screening completion within 6 months of outreach and the choice of colonoscopy as a screening test among those who completed screening at 4 and 6 months. **DV Measure:**CRCs screening completion	**Statistical:** 4 months, the CRC screening completion rates were 14.4% (95% CI, 8.7%-20.1%) in the colonoscopy-only arm, 17.1% (95% CI, 11.0%-23.2%) in the sequential choice arm, and 19.9% (95% CI, 13.4%-26.4%) in the active choice arm. Among those who completed CRC screening at 4 months, 90.5% (95% CI, 78.0%-103.0%) chose colonoscopy in the colonoscopy-only arm, which was significantly higher than the 52.0% (95% CI, 32.4%-71.6%; P = .005) and 37.9% (95% CI, 20.2%-55.6%; P < .001) in the sequential choice and active choice arms, respectively. **Conclusion:** The researchers note that there was no significant increase in CRC screening when offering sequential or active choice, but there was a lower rate of colonoscopy in the choice arms than in the colonoscopy-only arm. Therefore, small changes in sequencing or defaults can affect patient decision making concerning preventive health.

Brenner, A. T., Rhode, J., Yang, J. Y., Baker, D., Drechsel, R., Plescia, M., Reuland, D. S., Wroth, T., & Wheeler, S. B. (2018). Comparative effectiveness of mailed reminders with and without fecal immunochemical tests for Medicaid beneficiaries at a large county health department: A randomized controlled trial. *Cancer*, *124*(16), 3346–3354. https://doi.org/10.1002/cncr.31566			**Level and Quality** **Level:1** – research is an RCT. **Grade A** – Large enough sample size, heterogenous sample, high levels of generalizability		
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
To compare whether a mailed CRC screening reminder with and without a FIT can affect CRC screening among Medicaid beneficiaries in an urban health department.	Randomized Controlled Trial	**Sampling Technique:** Random sampling **Participants:** 2,144 Medicaid beneficiaries at average CRC risk and no evidence of screening using Medicaid claims data. **Setting;** Mecklenburg health department **Excluded:** Those that did not meet criteria (reasons include, bad address and no longer enrolled in Medicaid) **Accepted-:** N=1500 all eligible for trial. **Control**= 726, **Intervention**=764 **Power analysis:** unable to determine	**Control protocol:** mailed CRC screening reminder without FIT **Intervention** The first group (Reminder + FIT Group) received a packet with a letter encouraging screening completion and a FIT kit with instructions for completion. The control group (Reminder Group) received the same letter with instructions for obtaining a FIT kit from the health department either in person or by mail. All participants who returned a completed FIT were notified of their results by mail or by phone, and those with abnormal (positive) FIT results received navigation to follow-up care from local Medicaid care coordinators. **Treatment/Fidelity:** For generalizable results, the study was conducted in a county with prior claims-based analyses as having among the lowest rates of CRC testing among Medicaid beneficiaries in the state of North Carolina. The study used a 1:1 ratio of sampling done through computer randomization to reduce bias.	Primary outcome = screening completion rates **DV measurement** The number of people who have completed CRC screening.	**Statistical** FIT return was significantly higher in the Reminder + FIT Group than the Reminder Group (21.1% vs 12.3%; difference 8.8%; 95% CI 3.7%, 13.9%; $p<0.01$). **Conclusion** A health department-based mailed FIT program targeting Medicaid beneficiaries was feasible. Including a FIT kit resulted in greater screening completion than a reminder letter alone.

Dougherty, M. K., Brenner, A. T., Crockett, S. D., Gupta, S., Wheeler, S. B., Coker-Schwimmer, M., Cubillos, L., Malo, T., & Reuland, D. S. (2018). Evaluation of Interventions Intended to Increase Colorectal Cancer Screening Rates in the United States: A Systematic Review and Meta-analysis. *JAMA Internal Medicine*, *178*(12), 1645–1658. https://doi.org/10.1001/jamainternmed.2018.4637			**Level and Quality** **Level 1** – Systematic review of RCTs. **Grade A** - Rigorous selection criteria and high generalizability.		
Purpose or Hypothesis	**Type of Evidence and Research Design**	**Sample (population, size, setting)**	**Intervention Procedures**	**Primary Outcome/Measures**	**Results Conclusions**
To identify interventions associated with increasing CRC screening rates and their effect sizes	Systematic review and meta-analysis of randomized clinical trials of US-based interventions in clinical settings.	**Sampling Technique:** systematic review and meta-analysis according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines **Participants:** randomized clinical trials (RCTs) of interventions intended to improve completion of any CRC screening test **Setting**; Clinical **Excluded:** **259** Full-text studies excluded **9** Not original research **16** Wrong population **18** Wrong screening or intervention **3** Wrong or no comparator **87** Wrong or no outcome **27** Wrong setting **28** non-US country **17** Wrong study design **3** Did not address KQ **0** non-English language **19** Abstract-only record **6** Published before 1996 CRC USPSTF guidelines **26** High ROB **Accepted:** 73 RCT	**Control protocol:** Usual non-multicomponent intervention to CRC screening. **Intervention Protocol:** 181 intervention comparisons in 366,766 patients **Treatment Fidelity:** The researchers assessed risk of bias within studies according to PRISMA recommendations using a tool based on Agency for Healthcare Research and Quality guidance. The studies were ranked in relation to their risk profile from high to low, with those ranked high excluded from the systematic review	DV: completion of CRC screening. DV Measures: (1) initial CRC screening by any recommended modality, (2) colonoscopy after an abnormal initial screening test result, and (3) continued rounds of annual fecal blood tests (FBTs).	FOBT outreach and patient navigation, especially multi-component interventions showed increased CRCS rates in US trials

<table>
<tr><td colspan="3">Rawl, S. M., Christy, S. M., Perkins, S. M., Tong, Y., Krier, C., Wang, H. L., Huang, A. M., Laury, E., Rhyant, B., Lloyd, F., Willis, D. R., Imperiale, T. F., Myers, L. J., Springston, J., Skinner, C. S., & Champion, V. L. (2021). Computer-tailored intervention increases colorectal cancer screening among low-income African Americans in primary care: Results of a randomized trial. Preventive Medicine, 145, 106449. https://doi.org/10.1016/j.ypmed.2021.106449</td><td colspan="3">Level and Quality

Level 1 – The research is an RCT Grade A – Large enough population and consistent and conclusive evidence</td></tr>
<tr><td>Purpose or Hypothesis</td><td>Type of Evidence and Research Design</td><td>Sample (population, size, setting)</td><td>Intervention Procedures</td><td>Primary Outcome/Measures</td><td>Results Conclusions</td></tr>
<tr><td>The aim of the study was to assess the differences in screening rates among those receiving the computer-tailored intervention compared to nontailored brochure</td><td>Randomized controlled trial</td><td>Sampling Technique: Recruitment from 11 urban primary care clinics in Indianapolis, Indiana and Louisville, Kentucky: 5 community-based safety-net clinics; 4 Veterans Affairs Medical Center (VA) clinics; and 2 university-affiliated clinics.
Participants:
self-identified as Black or AA, were aged 51 to 80 years, not up to date with CRC screening and scheduled for an upcoming visit with their primary care provider.
Setting: 11 urban primary care clinics in Indianapolis, Indiana and Louisville, Kentucky: (5 community-based safety-net clinics; 4 Veterans Affairs Medical Center (VA) clinics; and 2 university-affiliated clinics).
Excluded: if they did not speak English or had a personal history of CRC, a medical condition that prohibited screening, or a cognitive, speech, or hearing impairment.
Accepted:817
Intervention:
1. Computer tailored- n=335
2. Non-tailored brochure- n=410
Power Analysis
80% power for the two-sided chi-square test of two proportions, with alpha = 0.05.</td><td>Control Group = Eligible patients receiving nontailored brochure

Intervention
computer-tailored intervention assessed a participant’s perceived risk, benefits and barriers to CRC screening, age, gender and family history in real time followed by tailored messages to support development of beliefs that would be most aligned with a decision to screen</td><td>DV:
CRC screening rates

DV Measure:
Number of patients who have completed CRC screening test and stool blood test (SBT) post intervention</td><td>The colonoscopy screening rate was higher among those receiving the computer-tailored intervention group compared to the nontailored brochure, but the difference was not significant</td></tr>
</table>

<table>
<tr><td colspan="5">Wong, M. C., Ching, J.Y., Huang, J., Wong, J. C., Lam, T. Y., Chan, V.C., Ng, S. K., Hui, Z.,Luk, A. K., Wu, J. C., & Chan, F. K. (2018).Effectiveness of reminder strategies on cancer screening adherence: A randomized controlled trial. The Journal of the Royal College of General Practitioners, 68(674),e604–e611.https://doi.org/10.3399/bjgp18X698369et al.,2018</td><td>Level and Quality

Level 1 – RCT Grade B – fair level of generalizability</td></tr>
<tr><td>Purpose or Hypothesis</td><td>Type of Evidence and Research Design</td><td>Sample (population, size, setting)</td><td>Intervention Procedures</td><td>Primary Outcome/Measures</td><td>Results Conclusions</td></tr>
<tr><td>To evaluate the effectiveness of delivering interactive telephone reminders versus SMS messages for improving persistent adherence to FIT screening when compared with usual care</td><td>Randomized controlled trial</td><td>Sampling Technique: Patients with negative FIT results in their first screening round

Participants:
629 asymptomatic individuals aged 40–70 years with a negative FIT
Setting: A community screening center in Hong Kong.
Excluded:
Subjects who had medical conditions rendering them unable to understand telephone or SMS messages, or who had no mobile phone, were excluded
Accepted: 600 patients
Control: – patients who received no communication -(n=210)
Intervention;
1. Text (n=212)
2. Phone messages (207)
Power Analysis;
600, with 200 subjects in each of the three groups. A power calculation indicates that a sample of 200 participants in each group would provide 80% power (at the 5% level) to detect an increase of 11% in the interactive phone call and automated SMS message groups, versus no increase in the control group, which is assumed to have a baseline return rate of FIT specimens of approximately 70%</td><td>Control protocol:
Comparison: Control group:
No communication
Intervention protocol:
Text group: One-way text messages to patient's cell phone with reminder about the importance of regular CRCS, and the time and place for of FIT kit pick up. Phone group: Call from healthcare professionals with same message as text group except that the screening participants were able to talk with healthcare professionals
Treatment/Fidelity:
The researchers conducted repeat tests and reminded participants of the same using email and telephone calls in different intervals. The researchers had a predetermined timeline which they followed and to remove the element of bias in randomizing the sampled participants, they used computer-generated numbers.</td><td>DV: adherence to yearly FIT screening

DV Measure: Change in adherence level to yearly FIT screening</td><td>FIT test returned on anniversary date:
86.5% Control
90.4% Text
95.1% Phone
(P = 0.010)
At 6 months return rate:
94.1%, Phone
90.0%, Text
86.0% Control (P = 0.022)
Compared with the control telephone group were significantly more likely return FIT test. (AOR = 2.73, 95% CI = 1.35 to 5.53, P = 0.005)
Conclusion
Text only intervention did not have a significant difference compared to the control group</td></tr>
</table>

Table 2

Evidence Synthesis

Project Title: Improving colorectal screenings in a health. Clinic			
JHNEBP Model Level	**Total Number of Sources**	**Author and Quality Rating of each study**	**Synthesis of Findings**
Level 1 Experimental study · Randomized Controlled Trial (RCT) · Systematic review of RCTs with or without meta-analysis	5 Randomized Controlled Trails (Coronado et al., 2018; Mehta et al., 2019; Brenner et al., 2018; Wong et al., 2018; Rawls et al., 2021) 1 systematic review of RCTs (Dougherty et al., 2018)	Mehta et al. A Coronado et al-A Brenner et al.-A Dougherty et al.-A Wong et al.-B Rawls et al.-A	The studies demonstrated strong evidence to support multi-component interventions to increase CRCS. The interventions were cost-effective Dougherty et al. (2018) found FOBT outreach and patient navigation, especially multi-component interventions showed increased CRCS rates in US trials. Brenner et al. (2018) was a health department-based mailed FIT program targeting Medicaid beneficiaries was feasible. Including a FIT kit resulted in greater screening completion than a reminder letter alone. Coronado et al. (2018) found with usual care clinics, intervention clinics (FIT kits, mailing material etc.) had significantly higher adjusted clinic-level proportion of participants who completed a FIT. Mehta et al. (2019) reported that there was no significant increase in CRC screening when offering sequential or active choice, but there was a lower rate of colonoscopy in the choice arms than in the colonoscopy-only arm. Therefore, small changes in sequencing or defaults can affect patient decision making concerning preventive health. Wong et al. (2018) found that those receiving telephone call from health professions were significantly more likely to return FIT test. Rawls et al. (2021) found the colonoscopy screening rate was higher among those receiving the computer-tailored intervention group compared to the nontailored brochure, but the difference was not significant Some of the differences in the studies included the setting in which the study was conducted, the model of intervention and the population. In the study by Wong et al., (2018, one of the shortcomings was that the study had a homogenous population which differed from other studies. Most of the studies had similar interventions containing at least a FIT test, with the control group having the usual CRC screening. Again, only Wong et al., compared two telephone strategies. Mehta et al. (2019) interventions were also slightly different compared to the other 5 studies. Some of the studies had three arm interventions while others had two. However, a common conclusion in four of the six studies was that a multimodal intervention was more effective compared to routine CRC screening in terms of adherence and screening completion rates. (Coronado et al., 2018; Mehta et al., 2019; Wong et al., 2018; Rawls et al., 2021)

Level II Quasi-experimental studies · Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis	Level – II -Systematic review of 20 RCTs, 1 quasi-experimental study, and 1 observational study (Issaka et al., 2019)	Issaka et al. - B	Issaka et al. (2019) found that multilevel interventions may accelerate improvements in CRC screening rates. The intervention and findings of this study are similar to the other four level 1 studies (Coronado et al., 2018; Brenner et al., 2018; Rawls et al., 2021; Dougherty et al., 2018)
Level III Non-experimental study · Systematic review of a combination of RCTs, quasi-experimental, and non-experimental studies, or non-experimental studies only, with or without meta-analysis · Qualitative study or systematic review of qualitative studies with or without meta-synthesis			
Level IV Opinion of respected authorities and/or reports of nationally recognized expert committees/consensus panels based on scientific evidence			
Level V Evidence obtained from literature reviews, quality improvement, program evaluation, financial evaluation, or case reports · Opinion of nationally recognized expert(s) based on experiential evidence			
Overall Quality Rating w/rational and Recommendation:			
Recommendations Based on Evidence Synthesis Based on the quality of evidence collected, out of the 7 studies, 6 were level 1 with five of the 6 being A grade studies. Only two studies were grade B with one study being level II. Therefore, the studies should be included as part of the evidence-based literature for the quality improvement interventions with the studies showing strong, compelling evidence, and consistent results which is indicative for a practice change.			

Table 3

Measurement Plan

Project Goals	Data Collection Procedures (who, how, when)	Name of Data Collection Tool
Structure: By September 4th, 2023 100 % of staff (MA and providers) will be introduced to the new process of ordering, mailing, completing FIT through a refresher session	Project Lead will conduct a pre survey before refresher session and a post survey after refresher session	Survey and attendance sheet within REDCap
Process: By Dec 11th, 2023, 100% of medical assistants and providers will order FIT for all eligible patients seen in clinic or virtual	Chart audit by Project Lead student Weekly	Chart Audit and lab tracking sheet
Process: By Dec 11th, 2023, 100% of patients provided with a FIT kit by mail or in person will receive a phone call 1 week later to remind them to return the kit.	CHW or RN will call patients within a week who were identified on the lab tracking sheet of having an outstanding FIT	Chart audit within REDcap
Outcome: By Dec 11th 100% of patients with FIT returned will have results followed-up by staff	Chart audit by Project Lead Weekly	Chart audit within REDcap
Outcome: By Dec 11th, 2023, the community clinic will increase FIT completion by 25%to 50% (for ages 45-75).	Chart audit by Project Lead Weekly	Chart Audit within EHR system

Figure 1

Fishbone

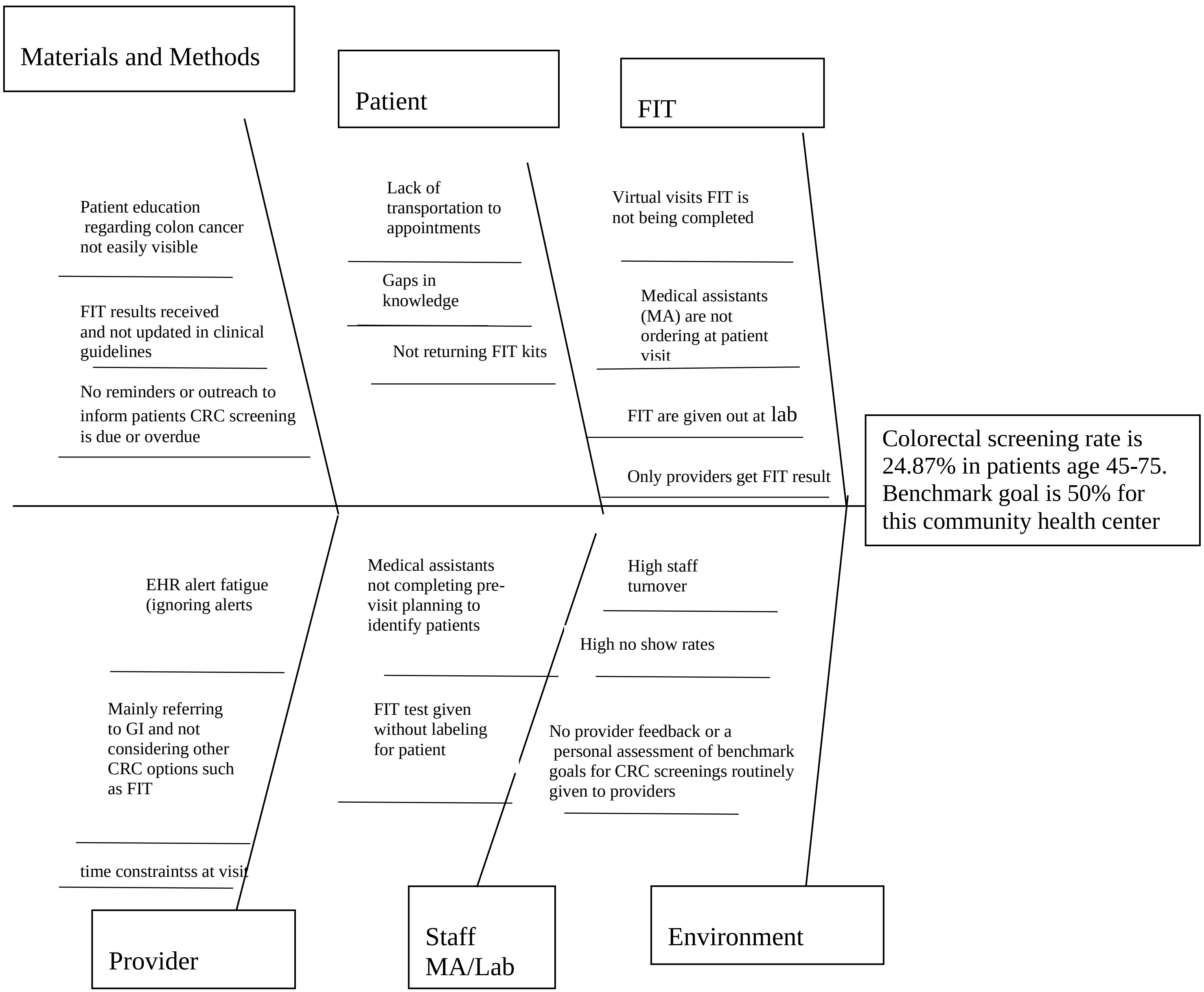
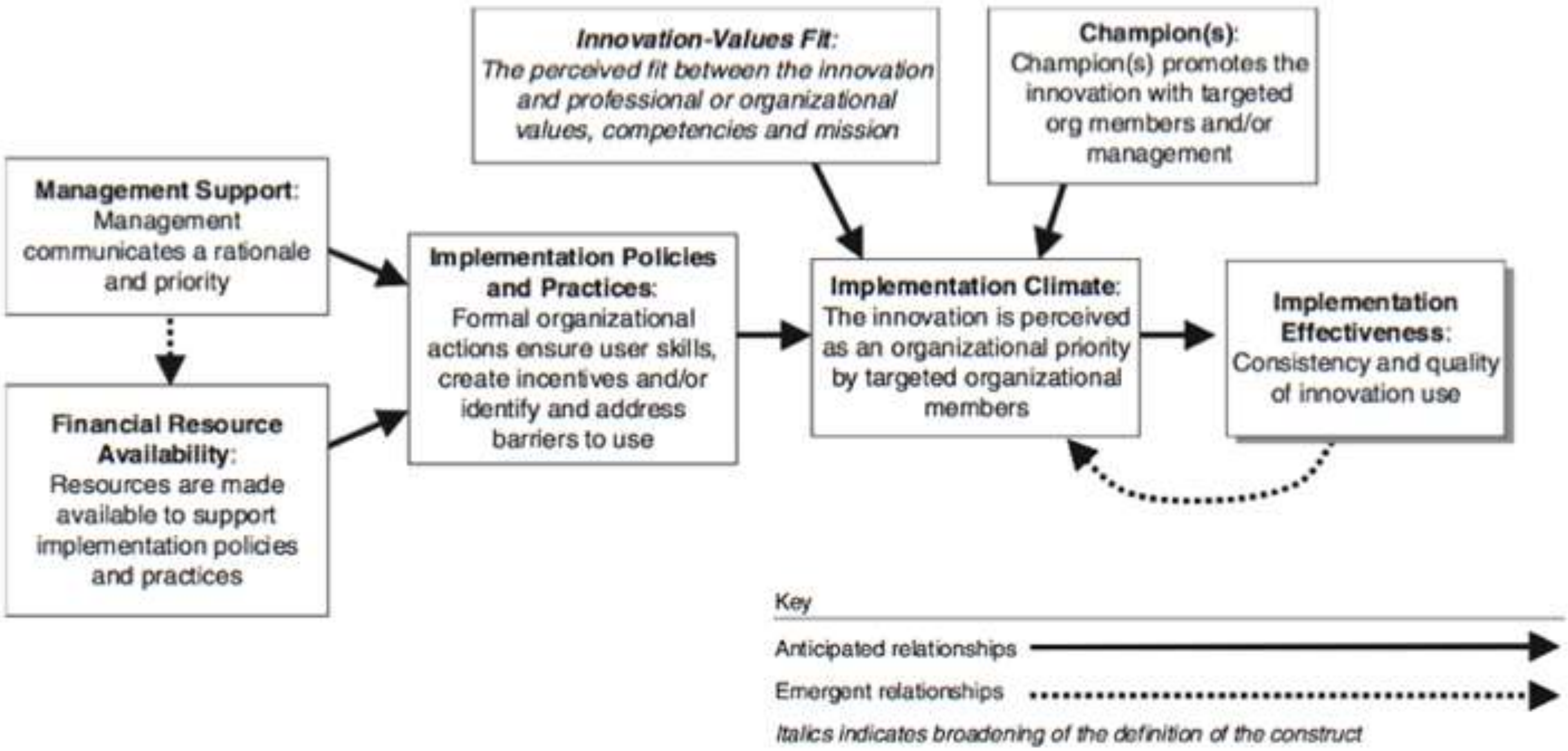


Figure 2

Complex Innovations Framework



Note: Adapted from https://umbnursing.softchalkcloud.com/lesson/serve/PGdKxrlbAMptf3/html

Figure 3

Process Map

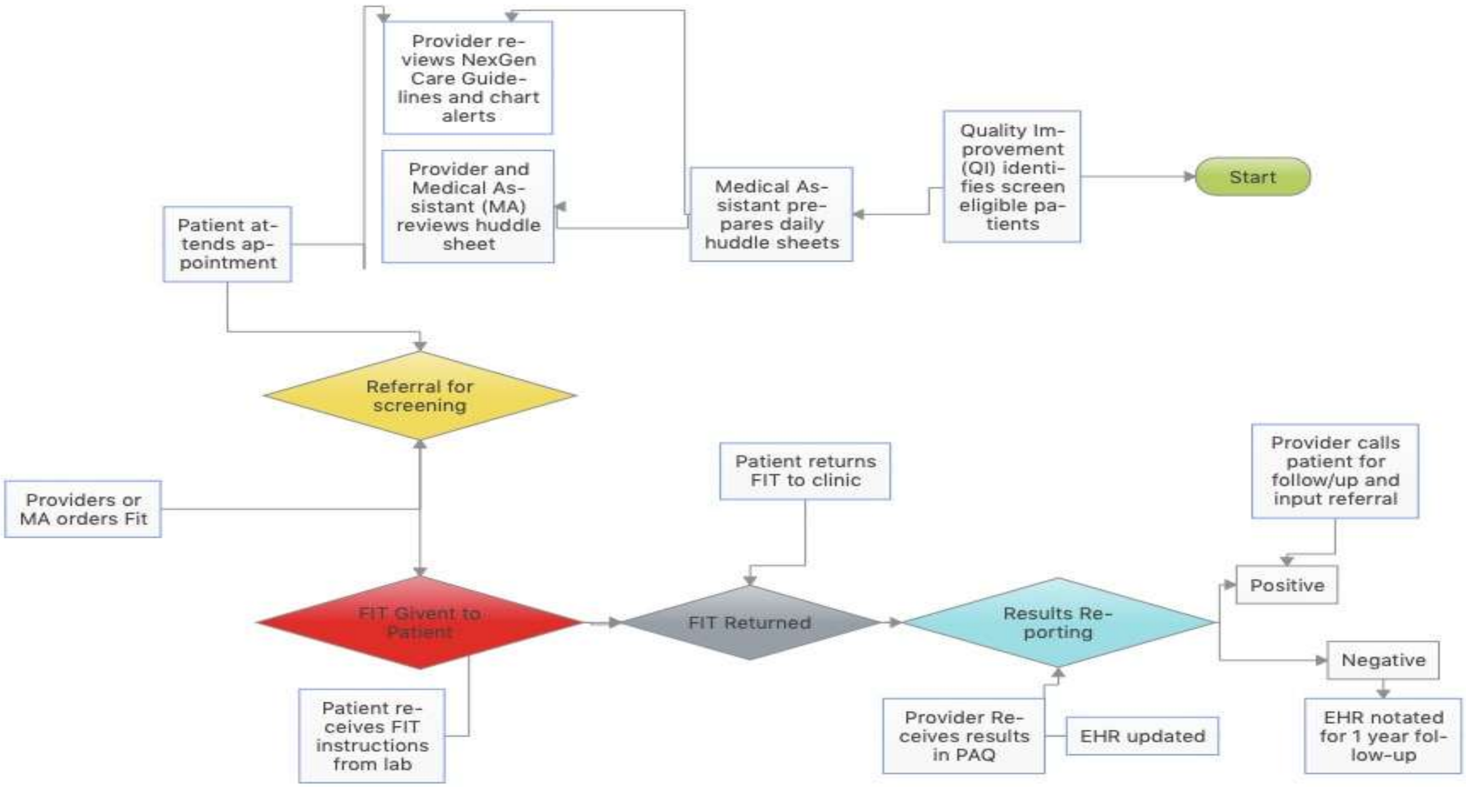


Figure 4

Process map with interventions

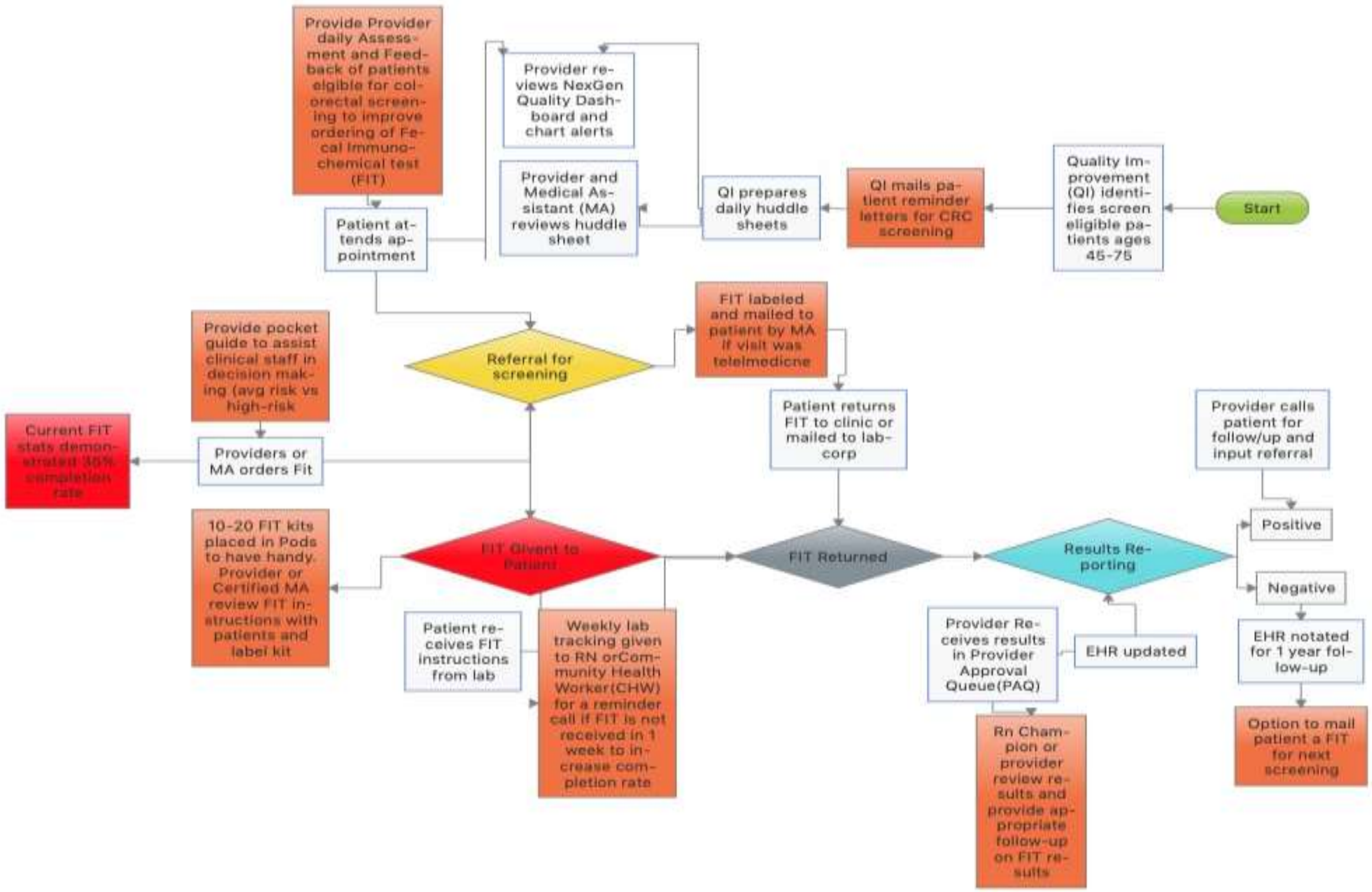


Figure 5

Phone Calls Reminders

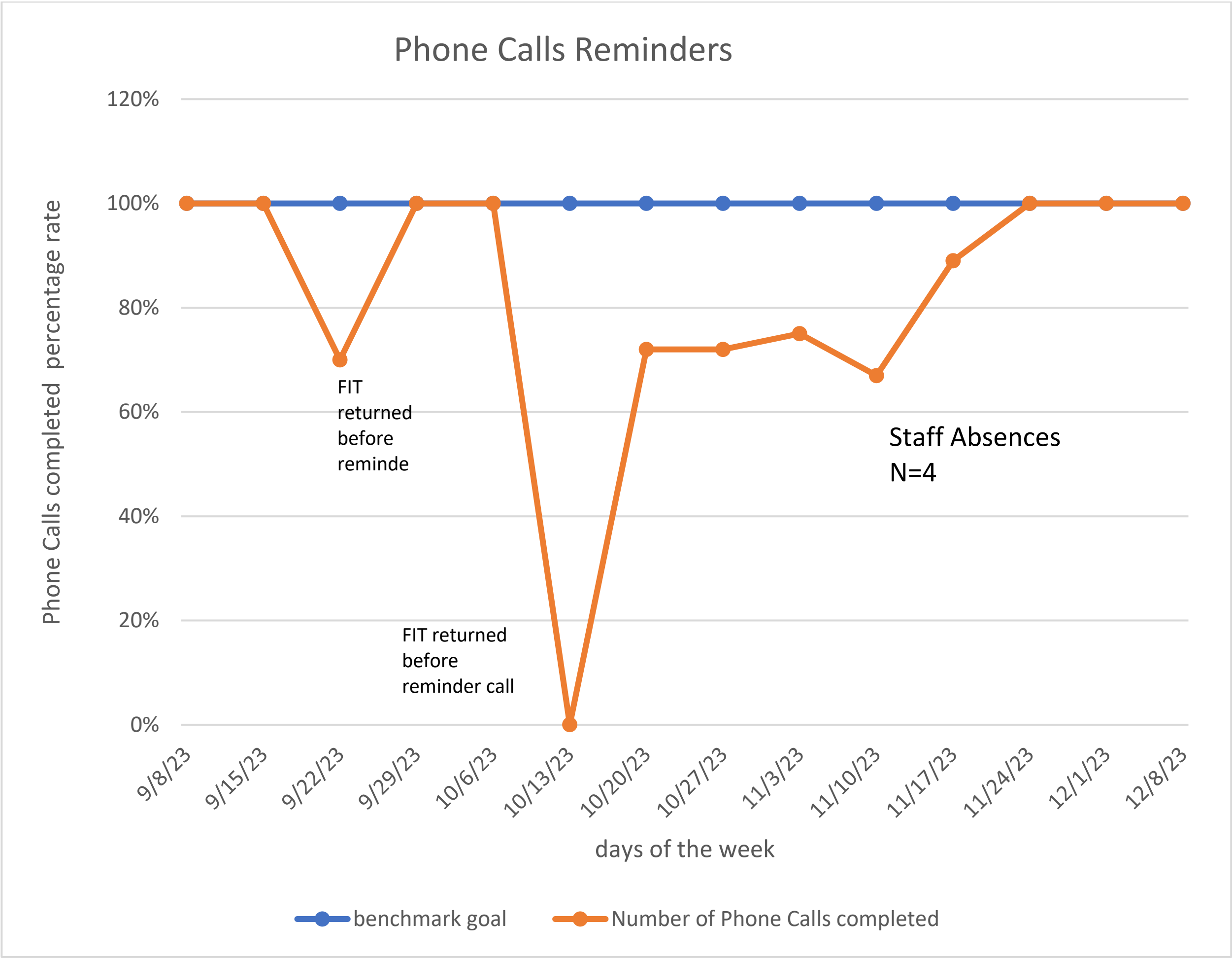


Figure 6

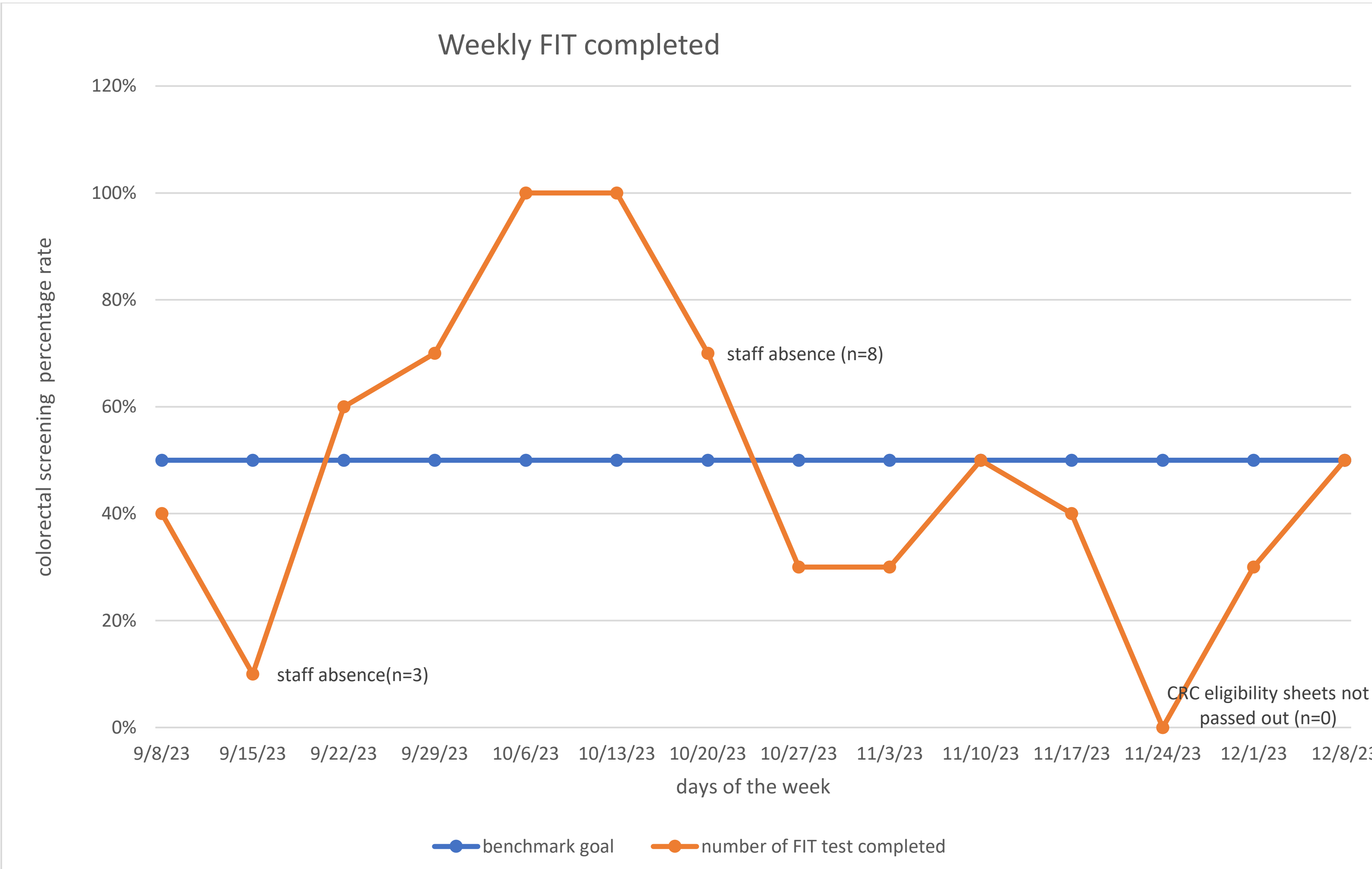
Follow-up for Completed FIT Results

Follow-up for Completed FIT Results

Eligible for FIT Screening	Number Completing FIT Screening	Staff FIT Results Follow- up
117	63 (54%)	63 (100%)

Figure 7

Weekly FIT Completed



Appendix A

Project Survey

Page 1

colorectal screening survey

Please complete the survey below.

Thank you!

1) How often did you present more than one test option while discussing colorectal cancer screening with your asymptomatic, average -risk patients during the past 12 months?
   - ○ Never
   - ○ Rarely
   - ○ Sometimes
   - ○ Usually

2) How often did you recommend any one particular colorectal cancer screening test or test combination over others while discussing colorectal cancer screening with your asymptomatic, average-risk patients during the past 12 months?
   - ○ NEVER
   - ○ Rarely
   - ○ Sometimes
   - ○ Usually

3) How often did your asymptomatic, average-risk patients wants you to decide which colorectal cancer screening test they should have during discussions of colorectal cancer screening in the past 12 months?
   - ○ Never
   - ○ Rarely
   - ○ Sometimes
   - ○ Usually

When you talk to your asymptomatic, average-risk patients about colorectal cancer screening, how often do you encounter the following?

		Never	Rarely	Sometimes	Usually
4)	Not having enough time to discuss screening with my patients	○	○	○	○
5)	Patients do not want to discuss colorectal screening	○	○	○	○
6)	Patients have diffculty understanding the information I present about colorectal cancer screening	○	○	○	○
7)	Patients are unaware of colorectal cancer screening	○	○	○	○
8)	Patients do not perceive colorectal cancer as a serious health threat	○	○	○	○
9)	Patients cannot afford or lack adequate insurance coverage for colorectal cancer screening	○	○	○	○

10) During a typical month, how many times do you order FIT screening?
   - ○ 0
   - ○ 1-10
   - ○ 11-20
   - ○ 21-40
   - ○ More than 40

11) who order FIT for your patients?
   - ○ I order
   - ○ Medical assistant
   - ○ I don't order FIT

03/12/2023 9:45pm projectredcap.org REDCap®

Adopted from National Cancer Institute (2023)

Appendix B

Attendance Sheet

Improving colorectal screenings in a community health clinic
Page 1

Colorectal Refresher Course Attendance

Date ______________________

Name ___________________________

Appendix C

FIT Chart Audit

Improving colorectal screenings in a community health clinic
Page 1

Chart Audit

Date	____________________
MRN	____________________
Date FIT Kit Sent	____________________
Phone Call Reminder Attempted	○ Yes ○ No
Phone Call Reminder Completed	○ Yes ○ No
FIT Kit Returned to Lab	○ Yes ○ No
Additional FIT Kit sent at Any Time	○ Yes ○ No
Did Staff follow-up with patient to review FIT results?	○ Yes ○ No

04/21/2023 9:48pm projectredcap.org REDCap