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A PROGRAM EVALUATION OF A COLON CANCER SCREENING PROGRAM USING AT-HOME FECAL IMMUNOCHEMICAL TESTS WITH CERTIFIED PATIENT NAVIGATORS

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A PROGRAM EVALUATION OF A
COLON CANCER SCREENING PROGRAM
USING AT-HOME FECAL IMMUNOCHEMICAL TESTS
WITH CERTIFIED PATIENT NAVIGATORS

CAPSTONE PROJECT PAPER

A paper submitted in partial fulfillment of the requirements for the degree of
Master of Public Health in the University of Kentucky, College of Public Health

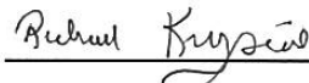
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Abbreviations

CLIA	Clinical Laboratory Improvement Amendments
CoC	Commission on Cancer
CI	Confidence Interval
CRC	Colorectal Cancer
FOBT	Fecal Occult Blood Test
LFCHD	Lexington-Fayette County Health Department
LOCF	Last Observation Carried Forward
FIT	Fecal Immunochemical Test
HPFPNI	Harold P. Freeman Patient Navigation Institute
IRB	Institutional Review Board
KCCSP	Kentucky Colon Cancer Screening Project
KCL	Kentucky CancerLink
PPV	Positive Predictive Value
Participants	Subset of patients in the Kentucky CancerLink Colon Cancer Screening Program included in this evaluation
Patients	All patients in the Kentucky CancerLink Colon Cancer Screening Program
Program	Kentucky CancerLink Colon Cancer Screening Program
RCT	Randomized Control Trial
UK	University of Kentucky

Abstract

Colorectal cancer is the second leading cause of cancer-related death in this country, but 33% of these deaths could be prevented by screening. While colonoscopy is an effective screening tool, it is expensive, invasive, and prone to encounter considerable patient resistance. An alternative is to first screen those at-risk using at-home fecal immunochemical test (FIT) kits. This study determined factors associated with the return of these kits distributed by Kentucky CancerLink, a non-profit organization, and its affiliates to participants in a colon cancer prevention program.

Objectives: To identify factors associated with: completing a FIT kit, completing the kit with minimal prompting, a positive FIT kit result, and a positive colonoscopy result. To evaluate a colon cancer screening program for internal and Commission on Cancer (CoC) implementation goals: ship kits promptly; notify patients and their physician, if requested, of FIT results promptly; follow-up on positive FIT results; encourage a high percentage of patients with a positive FIT to complete physician recommended follow-up; and evaluate effectiveness of follow-up contact policy.

Design: Descriptive

Setting: Non-profit organization in central Kentucky

Participants: The study analyzed data collected on 436 FIT kit participants, and 17 direct to colonoscopy participants, during the period January 1 through October 30, 2016. Participants were eligible if over 45 and African American or over 50 for all other races or family history of early-onset colon cancer or precancerous condition, Kentucky resident, and no history of colonoscopy in the past 5 years.

Outcome measures: FIT kit return, return of the FIT kit with 0-2 follow-up calls, FIT kit result, colonoscopy result, percentage of FIT kits shipped to participants in 0-2 business days, percentage of patients notified of FIT results in 0-2 business days, percentage of physicians notified in 0-2 business days, percentage of patients with positive FIT followed, percentage of patients with positive FIT who completed follow-up, number of calls and last attempt letters.

Results: Participants over 60 years of age had higher return rates than those under 60. Participants recruited via advertising, physician referrals, or health fairs had better return rates than participants recruited via church, work, or cold calls. Men were more likely than women to promptly return their kits. Caucasian: non-Hispanics were more likely to have a positive FIT result than African American or Hispanic & Other ethnicities. Participants referred by physician cold call list or advertising were more likely to have a positive FIT than those recruited via physician referrals, health fairs, church, or work. Participants directly referred to colonoscopy were more likely to have a positive finding on colonoscopy than those who had a positive FIT kit. The program met its goals statistically of shipping kits promptly and following up on positive FIT results. A policy of 3 follow-up calls and a last attempt letter was successful in encouraging the majority of participants to complete their kits.

Conclusions: While this study involved a relatively small sample size and cannot be generalized to a larger population, the value of evaluating a screening program, learning which methods of recruitment bear more fruit than others, and using that information can be generalized to other organizations, no matter the size of the

program. Patient navigators encouraged 73.62% of participants to complete their FIT kits through the use of follow-up calls and last attempt letters. Adults at greater risk of colon cancer responded well to the program. Adults over 60 were more likely to complete their kit. Men were more likely to complete their kit with minimal prompting. Patients who were screened directly to colonoscopy were more likely to have positive colonoscopy result. The program met its internal and CoC guidelines. These findings inform public health officials on how to allocate resources to maximize return of FIT kits in a colon cancer prevention program. Future programs would do well to recognize that participants themselves were still the rate limiting step, so patient navigators should put the kits in the hands of at-risk people, and remind them.

Background

While Kentuckians are proud of high rankings in competitive sports, such as college basketball, the legacy of high rates of colon cancer are not a source of bragging rights. Kentucky's age-adjusted incidence rate of colon cancer for 2010-2014 was 54.4/100,000 residents, with an African American incidence of 62.5/100,000 residents (Age-adjustment based on the 2000 US Standard Million Population). Fayette County fares slightly better at 48.2/100,000 for all races and 60.5/100,000 for African Americans. Age-adjusted incidence for KY males was 59.8/100,000 in the same period. [1] This doesn't compare favorably to US age-adjusted rates of 39.83/100,000 for the same period.

Colorectal cancer (CRC) is the second-leading cause of cancer-related death in the U.S., but a third of deaths could be prevented if at-risk people had regular

screening tests. [2] Healthy People 2020 states a goal of screening 70.50% of eligible people [3]. The Healthy Kentuckians 2020 initiative created Prev-1-2 to “Reduce invasive colorectal cancer” to “Improve screening rates...”, but no target nor CRC screening strategy was specified. [4]

One mechanism to improve screening is the use of FIT kits for general CRC screening of at-risk adults to detect occult (hidden) blood in the stool. While a colonoscopy is the gold standard of CRC screening, the FIT kit is an at-home screening test that requires only a small sample of normal stool, obtained in the privacy of the patient’s home. There is no preparation or special diet required. When compared to a colonoscopy, with its full day of restricted diet and colon cleansing preparation, plus another day for the test and recovery, the FIT kit is an appealing partner in CRC screening. Those with a positive FIT require follow-up care with their physician, which may include repeat FIT test, colonoscopy, sigmoidoscopy, etc. Those with a negative FIT, with their physician’s concurrence, may not need a colonoscopy. The American Cancer Society, the US Preventive Services Taskforce, and other organizations recommend “... a fecal immunochemical test (FIT) for screening, within the context of a high-quality stool-based screening” for annual CRC screening. [5]

Administering a CRC prevention program depends on proper identification of average risk adults for whom the FIT is advisable and those at higher risk for whom a colonoscopy is the better choice. Kentucky CancerLink (KCL), a non-profit organization in Lexington, KY, provides a CRC screening program to eligible Kentucky residents utilizing certified patient navigators who screen participants

using guidelines from the Kentucky Colon Cancer Screening Program (KCCSP) and direct them to the appropriate screening method. Navigators then shepherd patients through the screening process and encourage completion. Patient navigation originated with Harold P. Freeman in 1990 to reduce cancer care disparities. The Harold P. Freeman Patient Navigation Institute (HPFPNI) promotes standards and offers certification in patient navigation, with the primary goal "...to eliminate any and all barriers to timely screening, diagnosis, treatment, and supportive care for each individual." [6] KCL uses the FIT kits to get adults involved in screening, especially those opposed to colonoscopy, and as a useful monitoring tool between colonoscopy.

Literature Review

As with all medical screenings, the challenge is convincing participants to complete the test. A review of literature reveals a wide range of methods for encouraging participation.

Programs that don't appear to use navigators or reminders

Several articles reviewed did not specify how their patients were educated on the value of completing a screening test, nor did they specify the use of patient navigators or a reminder system to prompt compliance. Differences between studies can occasionally be inferred. For example, Daly (2010) mailed the FIT kit to 350 participants but only 87 (24.9%) were returned [7]. No mention was made of any communication or follow-up on the remaining 263 people. Crosby, et. al. describe a screening program with 345 participants in 8 rural Kentucky counties. Crosby's participant population is the closest geographically to the participant

population in this study. [8] Crosby included similar recruitment methods: health departments, advertising, and community outreach events. In this study 82.0% of participants returned their kits. No mention was made of efforts to prompt compliance once participants took the kit home. The differences between the return rates in the Daily and Crosby studies could lie in the fact that the Crosby group had a face-to-face interaction to complete a survey and receive the kit, while the Daly study mailed a kit.

Programs with some form of navigation or reminders

Several programs did utilize either patient navigators or some form of reminder system. The 2013 IRENE study, a randomized control trial in rural medical offices, found participation increased based on reminders “17.8% in the usual care group, 20.5% in the chart reminder group, 56.5% in the mailed education/FIT group, and **57.2% in the mailed education/FIT plus phone call group.**”[9]

The 2010 “Iowa Get Screened” project with over 400 participants yielded interesting results regarding the form of contact: “**Face-to-face recruitment** had the highest rate of returned FITs (**72%**) compared with handing the subject a research packet (3%) or a mailing only (9%).” Even with great FIT kit returns in the face-to-face group, this study reported difficulty convincing patients with a positive FIT to obtain a colonoscopy. [10]

Baker, et al. [11] described a Randomized Control Trial (RCT) of 450 patients who had previously completed a home Fecal Occult Blood Test (FOBT) kit. The control group received usual care – a FIT kit from a medical assistant. The intervention group received a mailed letter, a postage-paid return envelope, two “automated

telephone and text message”, and a navigator call if the kit was not returned within 3 months. The intervention group showed impressive results (82.2% vs 37.3%; $P < .001$).

In a 2013 article, a Texas RCT with uninsured patients found outreach to be significantly more effective than an office visit. They compared FIT, no-cost colonoscopy, and usual care, which consisted of an office visit followed by a physician recommendation of FIT, colonoscopy, barium enema, or sigmoidoscopy. Both the FIT and colonoscopy groups received automated messaging and two phone calls if not complete within 3 weeks. Randomization was not equal: FIT ($n = 1593$), colonoscopy ($n = 479$), and usual care ($n = 3898$). “Screening participation was significantly higher for both FIT (40.7%) and colonoscopy outreach (24.6%) than for usual care (12.1%) ($P < .001$).” [12]

In a multi-year RCT (2013-2016), Singal, et al. reported on nearly 6000 patients randomized to 3 groups similar to the Texas study: FIT ($n = 2400$), colonoscopy ($n = 2400$), or clinic-based screening ($n = 1199$). However, this study showed a preference for colonoscopy. They saw a dramatic difference in completion with “38.4% in the colonoscopy outreach group, 28.0% in the FIT outreach group, and 10.7% in the usual care group.” [13]

Kaiser Permanente clinics in California showed their creativity by offering a FLU-FIT program in 2009-2010 where eligible participants received a FIT kit along with their flu vaccination. Clinics served as their own controls by offering FLU-FIT on specified dates, and flu shots only with standard CRC screening activities on other dates. In the intervention arm ($n = 3351$) 26.9% of patients completed a FIT

compared with 11.7% in the control arm (n= 2884). Colonoscopy was not as well-received, with 2.6% and 2.1% completion respectively. [14] Patients who were reluctant to sign up for a colonoscopy saw the FIT kit as an innovation, a time-saving and less stressful way to complete their screening. Dr. Theodore R. Levin at Kaiser Permanente in California cites patient preference as being a key factor in their program's phenomenal success, "...we mail out over **500,000 FIT kits every year**, and **>60% are returned**... led to **screening rates above 83%** over the last 3 years." [15]

While that response rate is impressive, the FIT kit is not a panacea for low rates of colorectal screening. In the American Association for Cancer Research journal, Tim Byers of the Colorado School of Public Health cautions program planners by explaining the differences in colorectal cancer screening tests based on the goals of screening, which are to "...find cancers in an earlier, more treatable stage... To find and remove adenomas to prevent cancers from forming in the first place." Occult blood in the stool is a symptom of colorectal cancer, which would be identified by a FIT. However, benign tumors don't bleed, and won't be detected. Mr. Byers advises that "...direct endoscopic visualization of the colorectum is better for prevention." [16]

Perhaps combining efforts will reach more patients. The U.S. Preventive Services Task Force, the American Cancer Society, and an interdisciplinary task force convened by the Agency for Health Care Policy and Research, (now known as the Agency for Healthcare Research and Quality) [2] all recommend a combined approach of annual FIT kit plus periodic invasive testing with either sigmoidoscopy,

colonoscopy, or double contrast barium enema. So, which approach is best: wrangling patients into the invasive test every 5 or 10 years, or persuading them to complete the easier, annual test, PLUS a periodic invasive test? There is no clear answer. Proponents of FIT hope that completing the annual kit will condition patients toward regular screening, which will reduce barriers to thorough testing when needed.

Materials and Methods

The KCL program

This study evaluated the Kentucky CancerLink CRC screening program (program). This program was a collaborative effort with the Lexington-Fayette County Health Department (LFCHD) in Lexington, Kentucky, the University of Kentucky (UK), and the KCCSP. Program navigators were certified by HPFPNI [6], the George Washington University Cancer Institute [17], and the Patient-Centered Education & Research Institute [18]. The LFCHD and UK provided outreach services. KCCSP provided funding for FIT kits and no-cost colonoscopies to patients with positive kit results, or direct referral based on family history, who met eligibility requirements.

The program offered free at-home FIT kits to Kentucky residents. The kits were Polymedco OC-L (OC-Light) FIT-CHEK® kits. OC-L, OC-Light, and FIT-CHECK are registered trademarks of Polymedco, Inc. This kit was chosen because kits from prior years required two stool samples. The OC-Light kit required only one. The test measures hemoglobin in the patient's stool and can be used "for detecting

gastrointestinal bleeding associated with disorders such as colorectal cancer, polyps and colitis.”[19] The FIT kit contained:

- Patient consent to test and sample collection instructions in English or Spanish
- Collection materials: sampling tube with wand, plastic biohazard bag, and absorbent padding
- Self-sealing, postage-paid, return envelope addressed to KCL

Patient eligibility and recruitment

Patient eligibility for screening, both FIT and Direct to Colonoscopy, was based on guidelines from the KCCSP:

- Kentucky resident
- Age
 - 45 and older - African American
 - 50 and older - all other races
 - Younger participants qualified if they also met the High Risk guidelines
- No colonoscopy in the past 5 years

Patients screened for the following High Risk Guidelines were eligible for Direct to Colonoscopy:

- Previous diagnosis of colon or rectal cancer
- Previous removal of precancerous polyps

- Family history of colon cancer or precancerous polyps in one first degree relative or 2 or more second degree relatives younger than 60 at time of diagnosis
- History of ulcerative colitis or Crohn's Disease
- Increase in bright red blood from the rectum or bloody stools in the past 6 months
- Recent new diarrhea or constipation lasting longer than 2 weeks within the last 30 days
- Unexplained weight loss of more than 10% of body weight

Patient eligibility for no-cost colonoscopy, either direct or after a positive FIT, was based on additional guidelines from the KCCSP:

- Citizen or qualifying alien – had a social security number
- Legal resident of Kentucky
- Uninsured
- Income at or below 250% of the federal poverty level

Patients were recruited via Health Department/physician referral, advertising, and outreach events. March included heightened recruitment to coincide with CRC awareness month – increased events and advertising, which included television interviews, signs on public buses, and other media. Outreach events varied in size and service. Large public events offered FIT kits on the spot and education. Collaborative booths with the LFCHD at a Lexington mall and a church involved an inflatable colon through which shoppers could walk. Smaller events at worksites or churches offered FIT kits or collected contact information of interested

persons, based on the desires of the organizers. If kits were offered at an event, patients completed a questionnaire and received education on kit completion and follow-up. If kits were not offered at an event, the referrals were faxed to navigators for follow-up.

Partner physicians offered kits to patients during an office visit and faxed intake forms to KCL. All navigators, partner physicians, and outreach staff ensured that patient name and return address were annotated on the postage-paid envelope to return their stool sample to KCL for testing, and the name was recorded on the collection tube.

A federally-qualified health center collaborated with KCL. It provided a list of patients over age 50 who did not have a record of receiving a colonoscopy in the past five years for navigators to cold call and offer a kit. For all advertising, interested persons were directed to call KCL to request screening where navigators completed the questionnaire over the phone. For all other referrals, agencies faxed a referral form to KCL. Navigators called all referrals and completed questionnaires. See Appendix A for a sample client questionnaire. If the patient did not receive a kit directly from the referral source, a kit was mailed within two business days.

Electronic and paper records were created. Demographic data was collected upon initial contact with participants and entered into KCL's customized Microsoft Access database. Additional data was collected as part of the program: dates and details of patient interactions, lab results if kit returned, etc.

KCL patient navigation

All participants were followed by navigators. The first follow-up was set for 10 business days. Subsequent follow-ups were set for approximately 3-5 business days each at the discretion of the navigator, or at the request of the patient. Navigators contacted patients on follow-up days to encourage them to complete and mail their FIT kits, and to answer any questions. Patients were free to call KCL at any time with questions, and many did. A maximum of three follow-up calls were planned, after which navigators mailed a last attempt letter in English or Spanish.

Returned kits were tested in the KCL Clinical Laboratory Improvement Amendments (CLIA) certified lab on the day received. Kits delivered to the post office box on non-business days were picked up the next business day. Navigators contacted patients to report FIT results within two business days and faxed results to the patient's physician, if requested. If navigators could not reach a patient by phone, a letter was mailed with negative results, and a certified letter was mailed with positive test results.

In accordance with the Commission on Cancer (CoC) standards, "Each screening program has a process developed to follow up on all positive findings of participants" [20] navigators attempted to follow-up with all patients with a positive test. They educated patients on the need for follow-up care, referred them to their physician, and offered continued support. Follow-up recommendations included a colonoscopy, secondary FIT kit test, or other surveillance at the physician's discretion. If colonoscopy was advised, navigators contacted patients with

reminders for preparation, offered transportation services, and answered questions. Navigators assisted qualified uninsured patients with a positive FIT to receive a no-cost colonoscopy through the KCCSP. Navigators contacted patients after their procedures and received self-reported colonoscopy results: clear, polyps, or cancer.

Study protocol

This study composed descriptive statistics of participants and looked for factors associated with FIT kit completion, timing of completion, and results. The study also evaluated the program based on CoC guidelines for screening programs and KCL's internal benchmarks for success. The protocol was approved by the UK Institutional Review Board (IRB), project number 16-0132-P3H.

Study participant eligibility

Participants were eligible if they requested CRC screening between 1/1/2016 and 10/30/2016 and included follow-up data through 12/31/2016. Because program follow-up could take several months, the eligibility period was chosen to represent patients who enrolled between 1/1/2016 and 10/30/2016 to allow for patient follow-up completion by 12/31/2016. This range was chosen to provide a large sample size and to include patients who enrolled during both heightened recruitment (March) and normal recruitment to ensure program quality throughout the year. No attempt was made to balance the number of participants within each demographic factor level. Participant informed consent was waived because the study involved secondary data and did not require direct recruitment of participants.

Study data

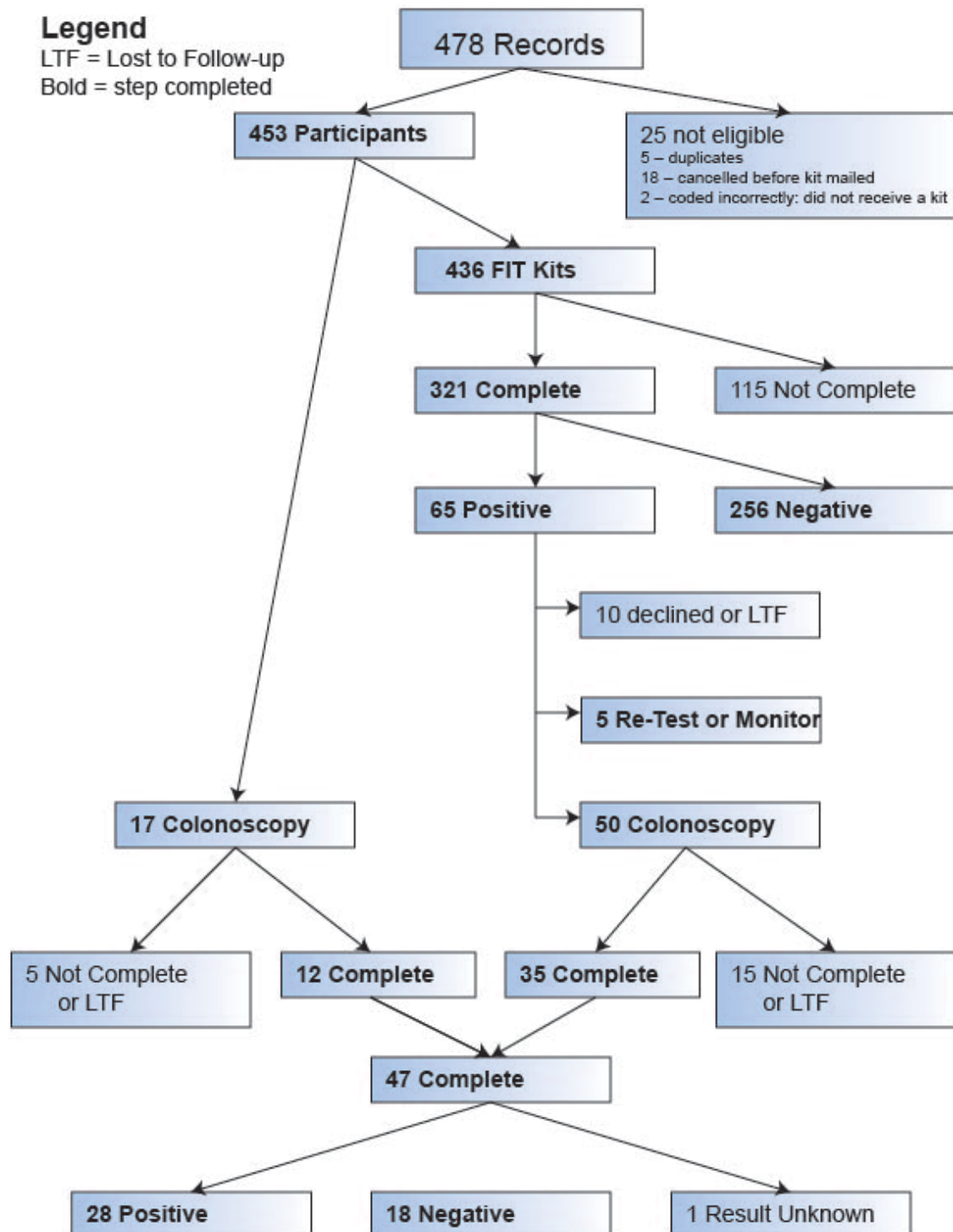
Data was extracted from the KCL Microsoft Access database, without patient information, as a Microsoft Excel file. Data was modified to prevent the possibility of patient re-identification, as per IRB requirements. See Appendix B for full details on dataset cleaning. Table 1 shows the data extracted vs. the study variables used.

Right-censored participants who did not complete follow-up prior to 12/31/2016 were included in the dataset (16). Any remaining follow-up was treated as not completed. Participant outcomes were tracked until all follow-up was completed, the participant was right-censored, or the participant was lost to follow-up. See Figure 1 for the participant outcomes flow diagram. A review of secondary data resulted in 478 records. The following records were excluded, resulting in 453 eligible participants:

- 5 – duplicate records
- 18 – participants cancelled their request before a FIT kit was mailed
- 2 – line item coded incorrectly: the participants did not receive a FIT kit as evidenced by content in follow-up call fields

Patients at higher risk for CRC received a colonoscopy instead of a FIT kit (17), as per KCCSP guidelines. Participant groups were split based on type of initial screening: resulting in 436 FIT kit participants and 17 direct colonoscopy participants. See Table 2 for demographic information.

Figure 1. Participant Outcome Flow Diagram



Hypotheses

The following hypotheses were formulated to answer the basic question of “How can the program identify patients at the greatest risk of CRC and assist them?” In order to assist patients with a positive result, the patient must complete the screening, so the primary goal was to identify those patients who are more likely to complete their screening. The program administrators also wanted to assess the amount of resources to invest in each patient: the differences between patients who will complete the kit with a small expenditure vs. those who require a large expenditure of time and resources.

Next, the program wanted to identify the differences between patients who have positive results on the FIT kit or colonoscopy, so the program could target these groups in future recruitment. Patients worry over any positive screening test. Therefore, navigators wanted to know the likelihood that a patient with a positive FIT would have a positive finding on a colonoscopy. Finally, program administrators wanted to know if the program reached its target population and if protocols were being followed, including the CoC requirement to follow-up on all positive screening results. Five hypotheses were chosen for this study:

1. Primary: Participants who completed the FIT kit are different from those who did not complete the kit.
2. Secondary: Participants who completed the FIT kit with little or no prompting (0-2 follow-up calls) are different from those who required more prompting (3 or more follow-up calls).

3. Secondary: Participants with a positive FIT kit result are different from those with a negative result.
4. Exploratory: Participants who completed a colonoscopy and had a positive result (polyps) are different from those with a negative result (no polyps). This hypothesis is exploratory only, due to the small sample size.
5. Exploratory: Program Evaluation:
 - a) The program shipped at least 80% of FIT kits within 2 business days after participant request.
 - b) The program notified at least 80% of participants of lab results within 2 business days after FIT kit returned.
 - c) The program notified at least 80% of participant's physicians, if provided, of lab results within 2 business days after FIT kit returned.
 - d) The program attempted to follow-up with 100% of participants with a positive FIT kit result, as per CoC guidelines.
 - e) At least 60% of participants with a positive FIT kit completed their physician's follow-up recommendation.
 - f) The program policy of 3 calls plus a last attempt letter produced the most cost-effective percentage of completed kits.

Statistical analysis

The hypotheses were tested, using SAS 9.4. For hypotheses 1 - 4, Univariate analysis was performed using PROC FREQ with a chi square test and alpha of 0.05 for all tests. Multivariate logistic regression was performed including each factor with a significant univariate result, and all two-way interactions. The

multivariate analysis used PROC LOGISTIC with stepwise reduction and alpha of 0.05. Odds ratios were calculated for levels of each factor found to be significant. For hypothesis 1 (difference between complete and not complete), the 436 FIT kit participants were analyzed. The primary endpoint was the FIT kit return. For hypothesis 2 (difference between completers by prompting level), the 321 participants who returned their FIT kit were analyzed. The endpoint was return of the FIT kit with 0-2 follow-up calls. For hypothesis 3 (difference between positive and negative FIT result), the 321 participants who returned their FIT kit were analyzed. The endpoint was the FIT kit result. For hypothesis 4 (difference between positive and negative colonoscopy result), the 35 participants with a positive FIT kit result who completed colonoscopy and 11 participants who were directly referred for colonoscopy were analyzed separately and combined. The endpoint was the colonoscopy result.

For hypotheses 5a - e, hand calculations were done as follows. The mean percentage of records in compliance was calculated by dividing the number of records in compliance by the total records X 100%. The standard error was calculated using the formula:

$$100 * \text{Square root } [p (1-p)) / n] \text{ where } p \text{ represents the proportion of records in compliance and } n \text{ represents the total records}$$

The 95% Confidence Interval (CI) was calculated using the formula: Mean percentage - + 1.96 (standard error). This method was chosen for simplicity. A test was considered significant if the lower bound of the 95% CI exceeded the desired percentage.

For hypothesis 5a (FIT kit shipping), the 436 FIT kit participants were analyzed. The percentage of FIT kits provided to participants in 0-2 business days was compared to 80%. For hypothesis 5b (patient notified of FIT result), the 321 participants who returned their FIT kit were analyzed. The percentage of patients notified in 0-2 business days was compared to 80%. For hypothesis 5c (physician notified of FIT result), the 237 participants who requested their FIT results be sent to their physician were analyzed. The percentage of physicians notified in 0-2 business days was compared to 80%. For hypothesis 5d (follow-up on positive FIT), the 65 participants with a positive FIT result were analyzed. The percentage of patients followed was compared to 100%. For hypothesis 5e (follow-up on positive FIT completed), the 65 participants with a positive FIT result were analyzed. The percentage of patients who completed follow-up was compared to 60%.

For hypothesis 5f (calls and last attempt letter), descriptive statistics were created using PROC MEANS. Frequency data was compared using PROC FREQ. The number of calls and last attempt letters for 434 FIT kit participants were compared. Two participant records were missing the number of calls. No test for significance was applied.

The alpha values were not corrected for multiple testing in any of the secondary or exploratory hypotheses because this study did not attempt to show causation or to craft a predictive model. The researcher acknowledges the fact that the risk of a type 1 error increases with multiple testing. The reader may interpret the results accordingly.

Results

Participants

Participants ranged in age from 24 to 96. Participants resided in 47 of the 120 counties in Kentucky. Fayette residents (253) dominated and combined with Jefferson (1) to comprise the urban category. All other counties combined to form the rural category (199) as described in Appendix B. A spacial analysis was not part of this study.

The FIT group mean age was 61.20 years. They were more often referred by outreach/health fair (48.6%). The majority were Caucasian: non-Hispanic (63.9%), lived in an urban county (56.0%), were female (61.9%), and were not current smokers (77.8%). The nature of the KCCSP guidelines placed more uninsured (78.6%) in the colonoscopy group.

The colonoscopy group mean age was 55.27 years. They were more often referred by physician/health dept. (47.1%). The majority were Caucasian: non-Hispanic (73.3%), lived in an urban county (58.8%), were male (88.2%), and were not current smokers (66.7%). Their insurance type was fairly well distributed between uninsured (16.5%), Medicaid (17.5%), Medicare (19.3%), private (23.7%), and other (22.9%).

1. Factors associated with completion

Primary hypothesis: Participants who completed the FIT kit are different from those who did not complete the kit. Of the 436 eligible participants who received a FIT kit, 321 (73.62%) completed the kit. See Table 3 for results.

Age (p-value 0.0118) and referral source (p-value 0.0020) were associated with completion of the FIT kit. After adjusting for referral source, the odds of completing the FIT kit for 50 – 59 year olds were 2.144 (1.009, 4.556) times that of participants under 50. Likewise, the odds for 60 – 69 year olds was 3.420 (1.560, 7.496), and participants 70 and older was 3.046 (1.298, 7.149). The confidence intervals do not include the null value of 1, which indicates there was a significant difference in the odds ratios between the groups.

After adjusting for age group, the odds of completing the FIT kit for participants referred by advertising were 4.626 (1.905, 11.230) times that of participants referred by cold call list. Likewise, the odds for participants referred by their physician or health department were 3.712 (1.532, 8.995), and by outreach/health fair were 2.692 (1.513, 4.790). The confidence intervals do not include the null value of 1, which indicates there was a significant difference in the odds ratios between the groups.

After adjusting for age group, the odds of completing the FIT kit for participants referred by church / work were 1.566 (0.665, 3.688) times that of participants referred by cold call list. The confidence interval includes the null value of 1, which indicates there was no difference in the odds ratios between the two groups.

Therefore, we reject the null hypothesis, and conclude there was a difference in demographic factors of age group and referral source between the participants in the study population who completed the FIT kit and those who did not.

2. Factors associated with completion with minimal prompting

Secondary hypothesis: Participants who completed the FIT kit with little or no prompting (0-2 follow-up calls) are different from those who required more prompting (3 or more follow-up calls). Of the 321 participants who completed the FIT kit, 267 (83.18%) completed the kit with little or no prompting, and 54 (16.82%) required more follow-up calls and letters. See Table 4 for results.

Sex was associated with completing the FIT kit with minimal prompting (p-value 0.0070). The odds of completing the FIT kit with minimal prompting for men were 2.568 (1.293, 5.099) times that of women. The confidence interval does not include the null value of 1, which indicates there was a significant difference in the odds ratios between the two groups. Therefore, we reject the null hypothesis, and conclude there was a difference in demographics between the participants who complete the FIT kit with minimal prompting in the study population.

3. Factors associated with positive FIT kit result

Secondary hypothesis: Participants with a positive FIT kit result were different from those with a negative result. Of the 321 participants who completed the FIT kit, 65 (20.25%) had a positive result. See Table 5 for results. Ethnicity (p-value 0.0140) and referral source (p-value 0.0045) were associated with a positive FIT kit result. After adjusting for referral source, a Caucasian: non-Hispanic patient had a 6.085 (1.295, 28.581) times greater odds of a positive test than a Hispanic & Other ethnicity patient. The confidence interval does not include the null value of 1, which indicates there was a significant difference in the odds ratios between the groups.

After adjusting for ethnicity, a participant referred by physician cold call list had a 4.255 (1.957, 9.250) times greater odds of a positive test, and advertising had a 2.278 (1.068, 4.858) times greater odds, than a patient referred by outreach/health fair. The confidence intervals do not include the null value of 1, which indicates there was a significant difference in the odds ratios between the groups. Therefore, we reject the null hypothesis, and conclude there was a difference in demographics between the participants with a positive FIT kit result and those with a negative result in the study population.

4. Factors associated with positive colonoscopy results

Exploratory hypothesis: Participants who completed a colonoscopy and had a positive result (polyps) are different from those with a negative result (no polyps). The participants who were directly referred for colonoscopy (17) were combined with the participants who had a positive FIT and were referred by their doctor for colonoscopy (50) for a total of 67 participants. Of the 67 participants, 47 (70.15%) completed the colonoscopy with 28 (60.87%) positive, 18 (39.13%) negative, and 1 lost to follow-up before results obtained. The route participants took to colonoscopy shows a marked difference in the outcome. Direct to colonoscopy participants were more likely to have a positive result (81.82%) than those with a positive FIT (54%). See Table 6 for results. None of the demographic factors for the two groups, nor the combined group, were significant. Therefore, we fail to reject the null hypothesis, and conclude there was not enough evidence to show a difference in demographics between the participants with a positive colonoscopy result and those with a negative result in the study population.

Positive Predictive Value

The Positive Predictive Value (PPV) was calculated for the study population as follows. Of the FIT kit participants with a positive FIT who completed colonoscopy (35), 19 were true positives and had a positive colonoscopy result. Dividing the 19 true positives by the 35 positive FITs yields a PPV of 54% for the FIT kit for the study population. Therefore, a participant with a positive FIT kit result had a 54% chance of having a polyp or other positive result on colonoscopy.

5. Program benchmarks

All hypotheses in the program evaluation were exploratory. Any missing data in hypotheses a-e was treated as Last Observation Carried Forward (LOCF) as a conservative approach; therefore, that record was coded as non-compliant. See Tables 7 and 8 for results.

- a) The program shipped at least 80% of FIT kits within 2 business days after participant request. The mean number of days to ship FIT kits was 0.86. The program exceeded its goal with 87.39% (95%CI 84.3%, 90.5%) shipped within 2 days. Therefore, we reject the null hypothesis, and conclude the program met this goal.
- b) The program notified at least 80% of participants of lab results within 2 business days after FIT kit returned. The mean number of days to notify patients was 1.28. The program met its goal with a raw percentage of 82.87% notified within 2 days, but not with statistical significance (95%CI 78.7%, 87.0%). Therefore, we fail to reject the null hypothesis, and conclude there was not enough evidence to show program compliance.

- c) The program notified at least 80% of participant's physician, if provided, of lab results within 2 business days after FIT kit returned. The mean number of days to notify physician was 1.18. The program met its goal with a raw percentage of 83.54% notified within 2 days, but not with statistical significance (95%CI 78.8%, 88.3%). Therefore, we fail to reject the null hypothesis, and conclude there was not enough evidence to show program compliance.
- d) The program attempted to follow-up with 100% of participants with a positive FIT kit result, as per CoC guidelines. The program met its goal with 100% followed. Therefore, we reject the null hypothesis, and conclude the program met this goal.
- e) At least 60% of participants with a positive FIT kit completed their physician's follow-up recommendation. The program met its goal with a raw percentage of 61.54% of participants completing follow-up, but not with statistical significance (95%CI 49.7%, 73.4%). Therefore, we fail to reject the null hypothesis, and conclude there was not enough evidence to show program compliance.
- f) The program policy of 3 calls plus a last attempt letter produced the most cost-effective percentage of returned kits. See Table 8 for results. The mean number of contacts for participants who completed the FIT kit was 1.18, with min of 0 and max of 10. The mean number of contacts for participants who did not complete the FIT kit was 3.38, with min of 0 and max of 9. The program policy of 3 calls plus a letter captured in 90.28% of participants who completed the kit. Therefore, we reject the null hypothesis, and conclude the program met this goal.

Harms

This study involved de-identified, secondary data. No breach in data security was found during the study. No known unintended effects occurred.

Discussion

The following discussion is focused on broad topics of demographics, positive FIT kit results, and program benchmarks

Demographics

A review of demographics across hypotheses shows interesting trends.

Referral source

Referral source had the most surprising results of all demographic factors. It was associated with FIT kit completion and positive FIT kit results; however, the most impactful source was not identical in both tests. Referral through advertising (84.48% complete) had the greatest impact on FIT kit completion, which was unexpected. Upon reflection, these participants had to receive the message and take action to request screening, and KCL staff noted a marked increase in phone calls immediately after each TV ad. Comparatively, those at a health fair simply had to approach the booth. The increased effort may have played a role. Participants who were less motivated to complete a test may have been less likely to make that first call. Referrals from the physician-supplied, cold call list (59.26% complete) had to answer the phone and agree to receive the screening, which required the least effort. Many insurance companies assign a primary care physician, but patients may have little or no contact with this provider. Hence, a recommendation received from an unknown doctor via a cold call may not motivate

as well as a locally-known TV personality interviewing the KCL director. And yet the cold call group had the highest percentage of positive FIT kit results (37.50%). Advertising ranked second (30.61%). Perhaps the health center generating the cold call list chose patients who were less apt to receive wellness visits; therefore, they were more likely to have a positive FIT.

Referral source was not statistically associated with positive colonoscopy findings (p-value 0.17); however, this hypothesis was exploratory due to the small sample size. Outreach/health fair participants had the highest percentage of positive finding (84.62%) even though they had a low percentage of positive FIT kit results (14.72%).

The disappointing result for the researcher was the church/work group. These participants should have had the most interaction with one another. It was hoped that discussions about the test would naturally arise as early completers received their results, which would prompt laggards to act. Yet, this group had low FIT kit completion response (60.53%), and the lowest positive results (8.70%). The work-based health fairs focused on Hispanic communities, where CRC incidence rates are lower [1], but where lack of insurance and regular health care is common. Church health fairs focused on African American communities where incidence is highest. Low sample size (38) may be the issue here. Disappointment in this area led the researcher to contemplate future studies with interactive methods to measure motivators.

Age

As expected, age played a role in this study. Age was associated with FIT kit completion (multivariate p-value 0.01), with the adjusted odds ratios of completing the kit increasing as age increased. While not statistically associated with positive FIT kits, the percentages of completion also rose with age (under 50 = 8.7% vs. over 70 = 25%). A similar result occurred for positive colonoscopy findings (50-59 = 50% vs. over 70 = 81.82%). Risk for CRC increases with age [1], so results indicating older Kentuckians are completing screenings are encouraging.

Sex

Male responses were encouraging. Both sexes returned FIT kits over 70% of the time, but men returned their kits with little or no prompting (90.4%). Men also saw more positive results on colonoscopy (70.37%) compared to women (47.37%). Men are at greater risk for CRC [1], so their strong participation in this screening was reassuring.

Ethnicity

Ethnicity was expected to play a larger role in positive FIT kit results and colonoscopy findings due to differences in CRC risk. [1] Ethnicity was associated with positive FIT kit results. Ethnicity was associated with FIT kit completion, but when adjusted for age and referral group in multivariate analysis, it was not significant. While the interaction between ethnicity and referral source was not significant, a confounding factor could exist. Caucasian: non-Hispanic participants outranked all other groups for FIT kit completion (77.74%), positive FIT kit results

(24.88%), and positive colonoscopy findings (64.10%). African Americans were expected to show higher positive results than their white counterparts.

Sample size again, could be the culprit. Caucasian: non-Hispanic participants (274) outnumbered African American (102) and Hispanic & Other (53). However, Kentucky's high rate of CRC could mean that the program simply did a better job of recruiting at-risk Caucasian: non-Hispanic participants than other ethnicities.

Colonoscopy results

The screening for higher-risk participants was effective, as evidenced by the higher rate of positive results on colonoscopy for the direct referrals than for those who first had a positive FIT. A PPV of 54% for the FIT kit for the study population matched a Canadian study that showed a PPV "for any neoplasia was 53%." [21] Most patients with a positive FIT want to know the likelihood that they "really need" that colonoscopy. This was a small sample size, so these results are not generalizable to all Kentuckians, but can be used to reassure patients of the need for follow-up. How this statistic is presented to patients can make the difference in their understanding of the importance of follow-up. If a navigator states, "You have a 54% chance of a positive finding on colonoscopy", the phrasing is less likely to prompt patients to make the commitment for the more invasive test. Instead, navigators could state that the FIT has been found to be reliable at predicting those who truly need their follow-up, including a small group of Kentuckians.

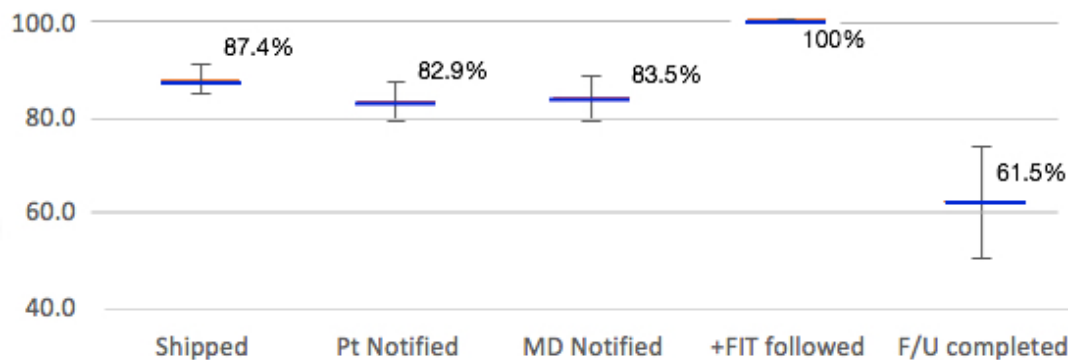
While demographics were not associated with positive colonoscopy, three factors had interesting results. The under 50 age group had a 2 of 3 participants with a positive result, which included more of the higher-risk participants. Otherwise, the

trend toward positive results increased with age from 50% in 50-59 to 81.82% in the 70 and over group. The outreach/health fair group had the highest percentage of positive results (84.62%). Males had a dramatically higher percentage of positive results (70.37%) than females (47.37%). The higher rate in older adults and males was expected, due to their higher risk of CRC. However, the association of referral source continues to puzzle the researcher.

Program benchmarks

The KCL program was successful in meeting all of its benchmarks from a clinical viewpoint. Statistically speaking, it met two criteria. This evaluation was exploratory, so strict adherence to statistical significance can be relaxed slightly. This was the program's first formal evaluation. As such, the benchmarks were set rather high. The CoC guideline for 100% patient follow-up after a positive finding is unforgiving, and the program still met that goal. Figure 2 below shows a summary of the benchmarks and their 95% Cis.

Figure 2. Program Benchmarks



Calls and letters

The KCL program did not adhere to the policy of only making 3 follow-up calls. This was at the discretion of the navigator and based on individual patient needs. Navigators reported that many people requested additional reminders due to vacations, busy work schedules, illness, etc. In addition, 33 participants either lost or had difficulty with their first kit and requested a second kit, which KCL mailed to them. This necessitated additional calls. All navigator contacts expend resources, so this review of the effectiveness of the additional contacts bears consideration.

Hypothesis not chosen

Program administrators wanted to know how effective their certified navigators were at encouraging patients to complete their kits compared to other programs. While this seemed like a simple question to answer, the mechanism to prove it was problematic. A randomized trial would certainly accomplish this goal. However, creating a control group without navigators and risking reduced completion for those patients was not compatible with the organization's mission.

After the literature review, a directly comparable program was not found. FIT kit return percentages and follow-up methods varied so dramatically that a single benchmark for comparison was not reasonable. This question was not chosen as a hypothesis, but is worthy of exploration by contrasting the program completion percentages to other screening programs. The IRENE study included follow-up calls with 57.2% complete "in the mailed education/FIT plus phone call group." [9] The Baker study also included text messages and calls and yielded an impressive 82.2% of kits returned. [11] The Crosby study return rate was also high at 82.0%.

[8] Of the 436 FIT participants in KCL program, 321 (73.62%) returned their kit. This puts the KCL program squarely in the ranks of successful programs.

Trends in positive FIT kit results

The study population had positive FIT kit results of 20.25%. During an informal evaluation in 2015, KCL program patients completed 374 FIT Kits with 27.81% positive. Kits from a different manufacturer were used in 2015 which required two stool samples, so these results were not directly comparable. However, there does appear to be a reduction in positive results. Some of the 2016 participants were repeat patients from the 2015 screenings, so a positive result in 2015 could have led to colonoscopy, polyp removal, and a negative 2016 test.

Limitations

This study had a number of limitations. Participants were not randomized, nor were balanced numbers of participants achieved in each level of category variables. The program recruited a good sample of African Americans (23.8%), but Caucasians made up the majority (63.9%). A large number of Kentucky counties were represented, but only a few participants were recruited from most of them. Fayette county residents made up 253 of total participants. Wider ethnic and geographic samples are needed. Without participant feedback, no inference can be made regarding motivating factors that influence compliance with CRC screening. These are topics for future research.

As discussed in the Statistical Analysis section above, this study explored multiple hypotheses but did not adjust the significance level. One hypothesis was chosen

as the primary. All others were considered as secondary or exploratory. The reader may apply an adjustment to significant results at his or her discretion.

Conclusions

Generalizability

This study did not seek to create a predictive model for future participant response. This was a first step to understanding the Kentucky population served by one non-profit organization; therefore, it is not generalizable to other populations. What may be generalized is the value of evaluating a screening program, learning which methods of recruitment bear more fruit than others, and using that information to direct resources and reassure stakeholders that the program adapts well to serve its population's needs.

Interpretation

These findings inform public health officials on how to allocate resources to maximize return of FIT kits in a CRC screening program. Adults at greater risk of colon cancer responded well to the program. Participants over 60 years of age had higher return rates than those under 60. Participants recruited via advertising, physician referrals or health fairs had better return rates than participants recruited via church, work, or cold calls. Men were more likely than women to promptly return their kits. Caucasian: non-Hispanics were more likely to have a positive FIT result than African American or Hispanic & Other ethnicities. Participants referred by physician cold call list or advertising were more likely to have a positive FIT than those recruited via physician referrals, health fairs, church, or work. Participants

directly referred to colonoscopy were more likely to have a positive finding on colonoscopy than those who had a positive FIT kit.

The program met its goals statistically of shipping kits promptly and following up on positive FIT kit results. Patient navigators encouraged 73.62% of participants to complete their FIT kits through the use of follow-up calls and last attempt letters. A policy of 3 follow-up calls and a last attempt letter was successful in encouraging the majority of participants who completed their kits. Future programs would do well to recognize that participants themselves were still the rate limiting step, so patient navigators should put the kits in the hands of at-risk people, and remind them.

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Tables

Table 1. Dataset variables

KCL Database	Study variable
Record Number	Used in data cleaning to convert long to wide, then deleted
Birthdate	Age – in years and categorical by decade
Ethnicity	Ethnicity – Caucasian: non-Hispanic, African American, Hispanic & Other
County of residence	County type – urban, rural to small town
Sex	Sex
Insurance – type (e.g. Medicare) or name of private company	Insurance type – Uninsured, Medicaid, Medicare, Private, Other
Smoking status	Current smoking status – Yes, No
Referral source – person, organization, health fair name, ad, etc.	Referral source - categorical
Annual income	Not used due to missing data
Line item – FIT, Colonoscopy	Initial Test – FIT, Colonoscopy
Date of initial contact	Used in data cleaning, then deleted
Date Kit mailed/handed to patient	Count of business days from initial contact to kit mailed/handed to patient
Dates of follow-up calls on FIT	Count of calls for FIT
Line item status – complete, cancelled, in progress	FIT status – complete, not complete Colonoscopy status – complete, not complete
Date and type of last attempt letter mailed	FIT letter – Yes, No Colonoscopy letter – Yes, No
Date FIT Kit returned	Count of business days from initial contact until FIT returned
Date second FIT kit mailed to patient	Second kit mailed – Yes, No
FIT results	FIT results
Date patient notified of FIT results	Count of business days from kit return until patient notified
Physician name if patient requested results sent	Physician results – Yes, No
Date physician notified of FIT results	Count of business days from kit return until physician notified
Dates of follow-up calls or registered letters after positive FIT	FIT Follow-up – Yes, No
Details of physician follow-up on positive FIT	Physician recommendation – Colonoscopy, repeat test, other monitoring, patient declined to share
Dates of follow-up calls on colonoscopy	Count of calls until Colonoscopy or other recommendation
Date of colonoscopy	Count of business days until Colonoscopy complete (from initial contact if direct to colonoscopy or from date of positive FIT)

KCL Database	Study variable
Colonoscopy results – polyps, benign polyps, precancerous polyps, etc.	Colonoscopy results – positive, negative

Table 2. Demographics

Data in columns 3 and 4 indicate Frequency (Column Percent), unless otherwise specified.

Factors	Levels	FIT kit n=436	Direct to Colonoscopy n=17
Age (continuous and categorical)	Mean Age (Standard Error)	61.20 (0.50)	55.27 (2.41)
	Median Age (Minimum Age, Maximum Age)	60.71 (24.14, 96.46)	56.77 (36.48, 71.64)
	Under 50	40 (9.3%)	4 (23.5%)
	50-59	162 (37.6%)	7 (41.2%)
	60-69	144 (33.4%)	5 (29.4%)
	70 and over	85 (19.7%)	1 (5.9%)
	Missing	5	
Referral Source	Physician/Health Dept.	47 (10.8%)	8 (47.1%)
	Outreach/Health Fair	212 (48.6%)	2 (11.8%)
	Church/Work	38 (8.7%)	
	Advertising	58 (13.3%)	3 (17.6%)
	Physician List/Cold Call	81 (18.6%)	4 (23.5%)
Ethnicity	African American	102 (23.8%)	1 (6.7%)
	Caucasian: non- Hispanic	274 (63.9%)	11 (73.3%)
	Hispanic & Other	53 (12.4%)	3 (20.0%)
	Missing	7	2
County	Rural to Small Town	192 (44.0%)	7 (41.2%)
	Urban	244 (56.0%)	10 (58.8%)
Sex	Male	166 (38.1%)	15 (88.2%)
	Female	270 (61.9%)	2 (11.8%)
Insurance	Uninsured	64 (16.5%)	11 (78.6%)
	Medicaid	68 (17.5%)	2 (14.3%)
	Medicare	75 (19.3%)	1 (7.1%)
	Private	92 (23.7%)	
	Other	89 (22.9%)	
	Missing	48	3
Current Smoking Status	Yes	80 (22.2%)	1 (33.3%)
	No	281 (77.8%)	2 (66.7%)
	Missing	75	14

Table 3. Factors Associated with FIT Kit Completion

Significant results highlighted.

Factors	Levels	n	Univariate p-value / % Complete by level	Multivariate Type 3 Analysis of Effects p-value Adjusted OR (95% CI) by level
Age			0.0347	0.0118
	Under 50	40	57.50%	1.00 reference
	50 – 59	162	72.22%	2.144 (1.009, 4.556)
	60 – 69	144	77.78%	3.420 (1.560, 7.496)
	70 and over	85	80.00%	3.046 (1.298, 7.149)
Referral source			0.0013	0.0020
	Physician List / Cold Call	81	59.26%	1.00 reference
	Advertising	58	84.48%	4.626 (1.905, 11.230)
	Physician/Health Dept.	47	80.85%	3.712 (1.532, 8.995)
	Outreach / Health Fair	212	76.89%	2.692 (1.513, 4.790)
	Church / Work	38	60.53%	1.566 (0.665, 3.688)
Ethnicity			0.0127	0.4611
	African American	102	62.75%	
	Caucasian: non- Hispanic	274	77.74%	
	Hispanic & Other	53	75.47%	
County			0.0198	0.3087
	Rural	192	79.17%	
	Urban	244	69.26%	
Sex			0.5332	--
	Male	166	75.30%	
	Female	270	72.59%	
Insurance Type			0.4272	--
	Private	92	79.35%	
	Medicaid	68	67.65%	
	Medicare	75	77.33%	
	Uninsured	64	79.69%	
	Other	89	74.16%	
Current Smoking Status			0.2160	--
	Yes	80	66.25%	
	No	281	73.31%	
Last Attempt Letter			<0.0001	
	Yes	127	24.41%	
	No	309	93.85%	
Interactions **	age*Ethnicity			--
	County*Referral			--
	Referral*age			--

Factors	Levels	n	Univariate p-value / % Complete by level	Multivariate Type 3 Analysis of Effects p-value Adjusted OR (95% CI) by level
	County*age			--
	County*Ethnicity			--
	Referral* Ethnicity			--

** All interaction models included an error message due to low sample size.

Table 4. Factors Associated with FIT Kit Completion with Minimal Prompting

Significant results highlighted.

Factors	Levels	n	Univariate p-value / % Complete by level	Multivariate Type 3 Analysis of Effects p-value OR (95% CI) by level
Age			0.5808	
	Under 50	23	73.91%	
	50 – 59	117	82.91%	
	60 – 69	112	85.71%	
	70 and over	68	82.35%	
Referral source			0.7286	
	Physician List / Cold Call	48	85.42%	
	Advertising	49	81.63%	
	Physician/Health Dept.	38	86.84%	
	Outreach / Health Fair	163	83.44%	
	Church / Work	23	73.91%	
Ethnicity			0.8890	
	African American	37	72.97	
	Caucasian: non-Hispanic	113	69.03	
	Hispanic & Other	22	68.18	
County			0.4425	
	Rural	152	84.87%	
	Urban	169	81.66%	
Sex			0.0057	0.0070
	Male	125	90.40%	2.568 (1.293, 5.099)
	Female	196	78.57%	1.00 reference
Insurance Type			0.8641	
	Private	73	84.93%	
	Medicaid	46	82.61%	
	Medicare	58	77.59%	
	Uninsured	51	82.35%	
	Other	66	83.33%	
Current Smoking Status			0.1935	
	Yes	23	79.25%	
	No	121	86.41%	
Interactions	N/A			

Table 5. Factors Associated with Positive FIT Kit Results

Significant results highlighted.

Factors	Levels	n	Univariate p-value / % Complete by level	Multivariate Type 3 Analysis of Effects p-value OR (95% CI) by level
Age			0.3780	
	Under 50	23	8.70%	
	50 – 59	117	21.37%	
	60 – 69	112	18.75%	
	70 and over	68	25.00%	
Referral source			0.0015	0.0045
	Physician List / Cold Call	48	37.50%	3.943 (0.788, 19.723)
	Advertising	49	30.61%	2.110 (0.399, 11.147)
	Physician/Health Dept.	38	15.79%	1.794 (0.309, 10.432)
	Outreach / Health Fair	163	14.72%	0.927 (0.187, 4.588)
	Church / Work	23	8.70%	1.00 Reference
Ethnicity			0.0063	0.0140
	African American	64	14.06%	2.433 (0.461, 12.840)
	Caucasian: non-Hispanic	213	24.88%	6.085 (1.295, 28.581)
	Hispanic & Other	40	5.00%	1.00 Reference
County			0.5367	
	Rural	152	21.71%	
	Urban	169	18.93%	
Sex			0.1817	
	Male	125	24.00%	
	Female	196	17.86%	
Insurance Type			0.4194	
	Private	73	17.81%	
	Medicaid	46	21.74%	
	Medicare	58	31.03%	
	Uninsured	51	19.61%	
	Other	66	19.70%	
Current Smoking Status			0.6013	
	Yes	53	22.64%	
	No	206	19.42%	
Interactions	Ethnicity* Referral			--

Table 6. Factors Associated with Positive Colonoscopy Results

Significant results highlighted.

Results are listed by route to colonoscopy (Positive FIT kit vs Direct) and as a combined group.

Factors	Levels	Positive FIT kit		Direct to Colonoscopy		Combined	
		n	Univariate p-value / % Complete by level	n	Univariate p-value / % Complete by level	n	Univariate p-value / % Complete by level
Age			0.0997		0.8214		0.3774
	Under 50	0	--	3	66.67%	3	66.67%
	50 – 59	14	35.71%	6	83.33%	20	50.00%
	60 – 69	11	54.55%	1	100%	12	58.33%
	70 and over	10	80.00%	1	100%	11	81.82%
Reference Group			0.2166		0.5648		0.1687
	Physician List / Cold Call	9		1	100%	10	50.00%
	Advertising	11	45.45%	2	50.00%	13	46.15%
	Physician/ Health Dept.	3	33.33%	6	83.33%	9	66.67%
	Outreach / Health Fair	11	81.82%	2	100%	13	84.62%
	Church / Work	1	0%	0	--	1	0%
Ethnicity			0.4886		0.0811		0.3634
	African American	5	40.00%	1	100%	6	50.00%
	Caucasian: non-Hispanic	30	56.67%	9	88.89%	39	64.10%
	Hispanic & Other	0	--	1	0%	1	0%
County			0.0599		0.0868		0.3306
	Rural	18	38.89%	6	100%	24	54.17%
	Urban	17	70.59%	5	60.00%	22	68.18%
Sex			0.4042		0.1971		0.1155
	Male	18	61.11%	9	88.89%	27	70.37%
	Female	17	47.06%	2	50.00%	19	47.37%
Insurance Type			0.5259		0.7622		0.4531
	Private	6	33.33%	0	--	6	33.33%
	Medicaid	5	80.00%	1	100%	6	83.33%
	Medicare	11	63.64%	1	100%	12	66.67%
	Uninsured	7	42.86%	9	77.78%	16	62.50%
	Other	6	50.00%	0	--	6	50.00%
			1.000		0.3865		0.6820

Factors	Levels	Positive FIT kit		Direct to Colonoscopy		Combined	
		n	Univariate p-value / % Complete by level	n	Univariate p-value / % Complete by level	n	Univariate p-value / % Complete by level
Current Smoking Status	Yes	4	50.00%	1	100%	5	60.00%
	No	24	50.00%	2	50.00%	26	50.00%
Interactions							

Chi square may not be valid due to small sample sizes. Some cell counts less than 5.

No statistically significant factors identified.

Table 7. Factors Associated with Program Benchmarks

Significant results highlighted.

Benchmark	Levels	n	Mean, (95% CI)
80% Kits mailed within 2 business days	Yes	381	87.39%, (84.3%, 90.5%)
	No	55	
80% Patients notified within 2 business days of returned kit	Yes	266	82.87%, (78.7%, 87.0%)
	No	55	
80% Physicians notified within 2 business days of returned kit	Yes	198	83.54%, (78.8%, 88.3%)
	No	39	
100% Follow-up on positive screening	Yes	65	100% (100%, 100%)
	No	0	
60% patients with positive FIT completed follow-up	Yes	40	61.54% (49.7%, 73.4%)
	No	25	

Table 8. Contacts Associated with FIT Kit Completion

Contact Type	Levels	n	% Complete by level	Mean (Std Error) Median (Min, Max)	Cumulative Percent
Calls	Complete	32 1	73.62%	1.18 (0.09) 1.00 (0.00, 10.00)	
	Not Complete	11 5		3.38 (0.13) 3.00 (0.00, 9.00)	
Last attempt letters sent	Complete	31	9.66%		
	Not Complete	96			
Combined Contacts (calls and last attempt letters) for Completed FITS	0 calls	14 5	45.45%		45.45%
	0 calls + letter	1	0.31%		45.77%
	1 call	78	24.45%		70.22%
	1 call + letter	1	0.31%		70.53%
	2 calls	38	11.91%		82.45%
	2 calls + letter	4	1.25%		83.70%
	3 calls	13	4.08%		87.77%
	3 calls + letter	8	2.51%		90.28%
	4 calls	10	3.13%		93.42%
	4 calls + letter	9	2.82%		96.24%
	5 calls	4	1.25%		97.49%
	5 calls + letter	2	0.63%		98.12%
	6 calls + letter	3	0.94%		99.06%
	7 calls + letter	1	0.31%		99.37%
	8 calls + letter	1	0.31%		99.69%
10 calls + letter	1	0.31		100.00%	

Appendix B Data De-Identification and Cleaning

The following is a detailed description of data de-identification and cleaning.

Data was de-identified using Excel 2016 to prevent the possibility of patient re-identification as follows:

- Converted long data to wide data (one record for each participant) using record number. Then, record number deleted.
- Birthdates converted to age. Then, birthdate deleted.
- Date Kit mailed/handed to patient converted to number of business days since kit requested.
- Dates of follow-up calls converted to count data of number of contacts before test completion. Two records identified as incorrectly in the line item. Follow-up call content related to a different screening program.
- Date Kit returned converted to number of business days since kit requested.
- Physician name converted to indicator for results requested to be sent to physician: Y or N.
- Patient and physician notification dates converted to number of business days since kit returned.
- Colonoscopy completion dates converted to number of business days since positive FIT.
- Dates of second kit mailed to patient converted to binary: Y or N.
- Dates of last attempt letter notifications converted to binary: Y or N.
- Dates of follow-up contacts on positive results converted to binary: Y or N.
- Dates of patient completion of follow-up on positive results converted to binary: Y or N.
- All date fields deleted.

All data extraction and de-identification was performed on KCL computers, which were password protected, encrypted, and physically protected behind multiple locked doors. The Excel file was transferred to an encrypted, password-protected flash drive, as per IRB guidelines.

Data was cleaned using SAS 9.4:

- Line Item status converted to two binary variables for FIT kit and Colonoscopy completion: Y or N. No includes 'in-progress', which are right-censored patients (16), and 'last attempt' (99). No missing data.
- Added a categorical ae variable to facilitate comparison between age ranges: Under 50, 50 – 59, 60 – 69, 70 and over. Age continuous variable was retained for demographic data, but was not used in hypothesis testing. 5 missing.
- Referral source (36 sources) was converted to categorical to reduce the number of sources and to de-identify the sources: advertising (TV, flyer, bus sign, etc.), physician/health department referral, outreach/health fair (excludes health fairs at a business or church), church/work health fair, cold call list (provided by a federally-qualified health center). No missing data.
- County of residence converted to binary: Rural (US census less than 50,000) vs. Urban (US census 50,000 or greater). [22] No missing data. Analysis was initially run with three categories of rural as defined by the USDA. However, low sample sizes in the rural counties resulted in cell values of 5 or less in some tests. Therefore, the three categories were combined to a single rural category.
- Sex - converted capitalization inconsistency, such as female vs. Female. No missing data.
- Ethnicity was condensed to three choices due to low sample sizes for some ethnicities: African American, Caucasian: non-Hispanic, Other. Other includes Caucasian: Hispanic/Latino (45), Arab (1), Indian (1), Asian (4), Brazilian (1), West Indian (1), and Other (3).
- Smoking status condensed to binary current smoking status due to low sample sizes: Y or N. No includes previous smokers (96), Never (179) and No (8). Unknown (85) was converted to missing. Smoking status was originally used with three options. However, during analysis of smaller groups, such as positive FITs, the small sample size resulted in chi square

tests with fewer than five participants in certain quadrants. Condensing smoking status solved this issue.

- Insurance was condensed to de-identify private insurance company names: Uninsured, Medicaid, Medicare, Private, Other. Private includes Anthem (2), KY Connect (1), Humana (1), and unnamed (1).
- Income field deleted due to 297 missing records.
- Education field deleted due to missing data for all records.
- Colonoscopy results converted to binary: Positive or Negative. Positive includes all forms of polyps or other abnormality detected, regardless of whether pathological findings were known.

Income information was missing on a large number of records. While some KCL programs require patients to disclose financial information, this program did not. Therefore, income was deleted for this study. Education was collected on the paper form. However, the KCL database did not offer a field for this information at the time of collection. It has since been updated to include this data field. The only method available to this researcher was to pull over 400 paper files and match the education information to the patient record number in the Excel spreadsheet. This action would have briefly re-identified the patient information, a violation of the IRB protocol. Therefore, education level was deleted for this study.

Biographical Sketch

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Candace Ellen Hall Brunk

eRA COMMONS USER NAME (credential, e.g., agency login): cebr222@uky.edu

POSITION TITLE: Masters Student

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Kentucky	MPH Advanced Certificate in Applied Statistics	Planned May 2018	Master's in Public Health, Biostatistics Concentration
Eastern Kentucky University Richmond, KY	B.S.	05/2015	Public Health Biology minor
US Air Force Brooks Air Force Base, TX		06/1984	Environmental Medicine
Kentucky Academy of Medical Massage Mayslick, KY		5/2009	Massage Therapy
Midwife at Heart Paris, KY		8/1998	Home-Birth Midwifery Apprenticeship

A. Personal Statement

My practical experience in public health began in the US Air Force in 1984. I was an Environmental Medicine Specialist, which is the military equivalent to civilian public health personnel. I ran a wide variety of initiatives, including infectious disease programs, such as tuberculosis, sexually transmitted diseases and the first military education on HTLV-III, the precursor designation to HIV.

I worked with Kentucky CancerLink (KCL) in Lexington, Kentucky during my 320-hour undergraduate practicum in Public Health through Eastern Kentucky University in the spring of 2015 and again for my 100-hour Masters practicum in 2016. My primary project was a colon cancer screening effort involving Fecal Immunochemical Test (FIT) at-home stool collection kits. This project involves over 400 participants and investigates factors that impact screening participation and program design/administration. I believe my project encompasses a broad selection of the core components of the Masters program: Biostatistics, Health Behavior, and Management.

I am fully capable of executing my proposed research. It may be ambitious for a Masters student, but I set high personal and professional goals. I've encountered surprise at my desire to choose such a challenging

endeavor. I hope to show that my committee's investment of time, funding, and advice in my career is well-founded.

B. Positions and Honors

Spring 2015 to present – Intern – Kentucky CancerLink – Lexington, KY - colon cancer screening project

2012 to present – Licensed Massage Therapist and Instructor – Lexington Healing Arts Academy – Lexington, KY – This work shows my love of teaching and in-depth knowledge of the human body. Advanced training in oncology massage. Oncology training externship supervisor at Baptist Health.

2006 to 2014 – Technical Writer – Lexmark International, Inc. and Perceptive Software, a division of Lexmark – Lexington, KY – This work shows my development as a technical writer and ability to craft technical documentation for any audience.

1994 to 2014 – Home Birth Midwife – A Midwife's Touch (sole proprietor) – Lexington, KY – This work shows my ability to adapt to changing situations, handle stress, educate patients, and provide personalized care for families throughout central KY. Being a sole proprietor shows my ability to manage my time and resources effectively.

1988 to 1994 – Variety of positions in desktop publishing and accounting – California and central KY – This work shows my ability to manage funds according to Generally-Accepted Accounting Principles (GAAP) and to craft quality documentation.

1984 – 1987 – Environmental Medicine Specialist – US Air Force – Hellenikon Air Base, Greece and Rhein Main Air Base, Germany – Comprehensive public health experience in environmental health, infectious disease control, and health education. – multiple Honor Graduate and Airman of the Quarter awards

C. Contribution to Science

As a Masters student, I cannot yet point to a list of published articles. However, as a home birth midwife, I contributed to the growing body of knowledge in the profession by training apprentices to become competent midwives.

As a Licensed Massage Therapist, I contribute to my profession by training future massage therapists. I contribute to oncology massage by training future therapists and collaborating with renowned researchers in the field, such as Gayle MacDonald.

As a Masters student I hope to contribute to science by crafting one or more articles from my capstone research for publication in peer-reviewed journals. I feel my research will yield insights into cancer screening programs, specifically the use of Diffusion of Innovations theory, the value of patient navigation, and the benefits of cancer screening programs.

D. Research Support

My undergraduate research in colon cancer screening at Kentucky CancerLink was my introduction to this work. The staff planned for a modest effort, but the program blossomed to over 700 participants, with over 350 completed within four months. I took on the task of collaborating with the office staff to devise new office procedures to adapt to the deluge of work. I trained other interns and volunteers and wrote detailed SOPs and scripts for use in the program.

Ongoing Research Support

I am not currently engaged in any other research.

Completed Research Support

I have not yet completed any independent research other than my internship experiences in 2015 and 2016.