2018

INCREASING COLORECTAL CANCER SCREENING IN KENTUCKY’S BUFFALO TRACE AREA DEVELOPMENT DISTRICT WITH A MAILED FIT PROGRAM

Carrie Anne Burt
University of Kentucky, carrie.burt@uky.edu

Recommended Citation
Burt, Carrie Anne, "INCREASING COLORECTAL CANCER SCREENING IN KENTUCKY’S BUFFALO TRACE AREA DEVELOPMENT DISTRICT WITH A MAILED FIT PROGRAM" (2018). Theses and Dissertations--Public Health (M.P.H. & Dr.P.H.). 207.
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Carrie Anne Burt, Student
Robin Vanderpool, DrPH, Major Professor
Dr. Corrine Williams, Director of Graduate Studies
INCREASING COLORECTAL CANCER SCREENING IN KENTUCKY’S BUFFALO TRACE AREA DEVELOPMENT DISTRICT WITH A MAILED FIT PROGRAM

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
By Carrie Anne Burt
Nicholasville, Kentucky

Lexington, Kentucky
April 19, 2018

Committee Chair: Robin Vanderpool, DrPH
Committee Member: Corrine Williams, ScD, MS
Committee Member: Richard Crosby, PhD
**Project Abstract/Summary**

This program involves a partnership among eight primary care clinics in the Buffalo Trace Area Development District (BTADD) of Kentucky and proposes implementing a mailed Fecal Immunochemical Test (FIT), or FIT Pack, program to increase colorectal cancer screening (CRCS) rates in this region. Mailing FIT tests to eligible patients is an evidence-based program that has been shown to increase CRCS among patients included in studies. The program will occur at the clinic level. Clinics will mail FITs and information leaflets to patients based on patient eligibility criteria identified in clinic electronic health records. The program’s short-term goals are to increase in CRCS among eligible patients, to increase colonoscopy referral among patients with positive FIT results, to increase provider knowledge of CRCS guidelines and strategies to increase CRCS, and to increase patient acceptance of recommended CRCS methods. Long-term outcomes will include an overall increase in CRCS in the BTADD, a reduction in late-stage colorectal cancer (CRC) diagnoses, a reduction in life-years lost to CRC, a reduction in CRC treatment-related morbidity and mortality, and an increase in overall community awareness and acceptance of CRCS methods. This program will partner with the Bracken, Fleming, Lewis, and Mason County PrimaryPlus Clinics, and the Fleming, Lewis, Bracken, and Buffalo Trace District Health Departments to identify and reach patients who are overdue for CRCS. Additionally, the Southern Ohio Medical Center, Buffalo Trace Gastroenterology, and the Meadowview Regional Medical Center will collaborate with clinic and program staff to serve as referral sites for colonoscopy or sources of additional information or expert opinions. Several local community representatives will contribute to the implementation plan for the FIT Pack program. Representatives from the Buffalo Trace District Cancer Council will assist with program promotion within the community. All activities in this program will be monitored and evaluated to ensure appropriate implementation and expected outcomes. The results from this project will be shared with other public health professionals at state and national conferences, including the American Public Health Association and Kentucky Public Health Association annual meetings.
Target Population and Need

Colorectal Cancer Incidence and Mortality

Colorectal cancer (CRC) is the third most common cancer among men and women and the third leading cause of cancer-related death in the United States (U.S.). Specifically, Kentucky ranks first in national incidence of CRC. From 2010 to 2014, Kentucky's age-adjusted incidence rate of CRC was 50.0 per 100,000, compared to the national average of 39.8 per 100,000. [1] From 2010 to 2014, there were also 17.2 reported CRC deaths per 100,000 Kentuckians compared to 14.5 CRC deaths nationally. Contributing to the disparity between Kentucky and the rest of the country is the elevated burden of CRC in Kentucky's rural counties. Figure 1 illustrates the area development districts (ADDs) that led the state in CRC incidence from 2011-2015, and Figure 2 illustrates the ADDs that led the state in CRC mortality from 2011-2015.

Figure 1. Age-Adjusted Colorectal Cancer Incidence Rates in Kentucky
Among the rural, underserved areas of Kentucky is the Buffalo Trace ADD, which includes Bracken, Fleming, Lewis, Mason, and Robertson counties (Figure 1 and 2). Of all the ADDs in the state, Buffalo Trace had the highest age-adjusted rate of CRC incidence from 2011-2015 at 62.5 cases per 100,000 residents. This is compared to the state age-adjusted CRC incidence of 53.0 during the same period. Not only was the overall cancer incidence higher in this area, the age-adjusted rate of invasive, or metastatic, CRC incidence was also second-highest in the state from 2011-2015 (58.9 versus 49.5 per 100,000). Finally, the Buffalo Trace ADD’s age-adjusted CRC mortality rate was higher than the rest of Kentucky from 2011-2015, with 27.2 deaths per 100,000 residents as compared to the state average of 16.8 deaths. [2]

In general, CRC affects men more than it affects women. From 2011-2015, the incidence rate among men in the Buffalo Trace ADD was 71.1 per 100,000 compared to the incidence rate of 55.4 among women in the ADD. Men from this area were also more likely to be diagnosed with invasive CRC; from 2011-2015, 68.0 men per 100,000 had late-stage disease at the time of diagnosis compared to 51.3 women. This disparity between the sexes
may indicate that men may not routinely adhere to CRCS guidelines. It follows that the age-adjusted CRC mortality rate was higher in men during this period as well; 30.6 men versus 25.1 women died from CRC in this geographic area from 2011-2015.[2]

**CRC Risk Factors**

CRC typically arises from the abnormal growth of polyps within the colon, which if left untreated can progress to cancer. There are a number of non-modifiable risk factors for CRC, including family history, genetics, age, and preexisting conditions such as ulcerative colitis. There are also modifiable risk factors for CRC, including a personal history of tobacco use, poor diet (especially diets high in saturated fat and red meats), and obesity.[3]

On average, 23.4% of Buffalo Trace ADD adults smoke, and 34% are obese.[4]

Although education on the importance of smoking prevention and cessation and healthy eating are an integral part of cancer prevention, CRC morbidity and mortality can be reduced through early screening, detection, and intervention. If detected in its earliest stage, when the cancer is localized to the colon or rectum alone, the 5-year survival rate for CRC is 90%. However, once in later stages when the cancer has metastasized, 5-year survival declines to just 14%.[5]

**CRCS**

The U.S. Preventive Services Task Force (USPSTF) recommends CRCS for average-risk adults age 50-75 years.[6] There are a variety of CRCS methods, including both point-of-care testing using a stool sample to detect the presence of blood, clinical imaging procedures that require anesthesia, and the use of endoscopy to view the tissue of the colon and rectum. The summary of the USPSTF recommendations for CRCS and their frequency is provided in **Table 2**.
Table 2. USPSTF Recommendations for Frequency of CRC[6]

<table>
<thead>
<tr>
<th>Screening Method</th>
<th>Recommended Frequency of Screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stool-Based Tests</td>
<td></td>
</tr>
<tr>
<td>gFOBT*</td>
<td>Yearly</td>
</tr>
<tr>
<td>FIT*</td>
<td>Yearly</td>
</tr>
<tr>
<td>FIT-DNA*</td>
<td>Every 1-3 years</td>
</tr>
<tr>
<td>Clinical Direct Visualization Tests</td>
<td></td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>Every 10 years</td>
</tr>
<tr>
<td>CT Colonography</td>
<td>Every 5 years</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy</td>
<td>Every 5 years</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy with FIT</td>
<td>Flexible sigmoidoscopy every 10 years, FIT yearly</td>
</tr>
</tbody>
</table>

*FIT=fecal immunochemical test; FIT-DNA=stool DNA test; gFOBT = guaiac-based fecal occult blood test

Of the stool-based tests, the USPSTF recommends the fecal immunochemical test (FIT) as a first-line screening strategy given that it is more accurate than the fecal occult blood test (FOBT) and requires only one stool sample rather than several samples. Of the direct visualization tests, colonoscopy is most commonly used in the U.S. Sigmoidoscopy use has declined nationally, and computed tomography (CT) colonography is currently less favorable than colonoscopy given the possibility that extracolonic findings may cause more harm to patients than good.[6]

Colonoscopy is beneficial in that polyps can be detected during the screening process, removed, and sent to pathology for testing. In many cases, patients need only return for routine follow-up after the removal of these polyps, as the colonoscopy itself is both diagnostic and therapeutic in nature. Alternatively, colonoscopy requires significant bowel preparation on the part of the patient, a clinic visit, sedation, caregiver support, and has a higher out-of-pocket cost than point-of-care testing. Following colonoscopy, patients cannot drive themselves home or return to work until the anesthesia has worn off. Thus, the process of colonoscopy is more cumbersome than stool-based tests.
Based on CDC Behavioral Risk Factor Surveillance System (BRFSS) data from 2017, 71.7% of Kentuckians age 50 and older have ever had a sigmoidoscopy or colonoscopy, but only 70.1% of Kentuckians are estimated to fully meet USPSTF recommendations for regular CRCS. In the Buffalo Trace ADD, the BRFSS estimates that a mere 64.6% of adults age 50 and older have ever had a colonoscopy or sigmoidoscopy, and only 61.8% of its residents are fully adherent to the USPSTF recommendations.[7] The BRFSS estimates that only 10.4% of adults age 50-75 received a blood stool test in 2016.[8]

In rural, Appalachian counties – which are some of the more medically underserved counties in the state of Kentucky – residents have cited a number of reasons for not having been screened for CRC. These reasons include: a lack of knowledge, inconsistent provider communication regarding CRCS, mistrust of the screening process (believing colonoscopy to be the only screening type), and fear of results.[9] While only Lewis County is the only county in the Buffalo Trace ADD that is considered Appalachian, these attitudes are likely still relevant in nearby rural non-Appalachian counties in the Buffalo Trace ADD. Given these gaps in knowledge, fears, and attitudes about the screening process, interventions focused on increasing CRCS rates have focused on provider communication and provision of stool-based tests for patients to use and return to the clinic for analysis.[10-13]

Buffero Trace ADD Resources for Implementation of a CRCS Program

Although the Buffalo Trace ADD does not have an ongoing CRCS program, it has several resources that support the implementation of one. Fleming, Lewis, and Bracken County each have their own independent health department; Mason and Robertson County share the Buffalo Trace District Health Department (BTDHD). Each of these health departments offers FOBTs on a sliding scale; it is unclear whether or not they have
included FIT kits in their inventory. The Meadowview Regional Medical Center (RMC) serves Mason County and offers both FOBT and FIT to patients on a sliding scale, as does the Southern Ohio Medical Center (SOMC) [Portsmouth, OH], which serves Lewis County. Finally, there are four PrimaryPlus Federally Qualified Health Centers (FQHCs) in the area, located in Bracken, Fleming, Lewis, and Mason Counties. These FQHCs also offer FOBT and FIT on a sliding scale. Each of these primary care facilities accepts Medicare, Medicaid, and all forms of private insurance.

In addition to the aforementioned primary care facilities, Buffalo Trace Gastroenterology in Mason County serves the area and offers FOBT, FIT, and colonoscopy. Buffalo Trace Gastroenterology and the Meadowview Regional Medical Center are the only clinics in the district that serve as a referral site for patients requiring colonoscopy. Although technically not within the Buffalo Trace ADD, the SOMC may also serve as a referral site for Lewis County patients requiring follow-up colonoscopy as well.

**Program Approach**

The proposed program will involve a partnership among the four health departments and four PrimaryPlus clinics in the Buffalo Trace ADD. The existing Buffalo Trace District Cancer Council (DCC) and Fleming County Cancer Coalition will also partner with the program to implement community-wide promotion efforts.

The eight total primary care clinic partners have selected an evidence-based strategy that entails mailing a FIT test to the patients home. Herein, the Buffalo Trace ADD program will be referred to as the FIT Pack program. An iteration of this program, implemented in the Parkland Health and Hospital System (PHHS) in Dallas, Texas, has been
recognized as a Research-Tested Intervention Program by the National Cancer Institute [14]. This program randomized participants to receive “usual care,” or CRCS at the discretion of his or her primary care provider at the time of visit, or a mailed invitation to screen for CRC with an accompanying FIT test or an appointment for a colonoscopy in clinic. This intervention was conducted in a racially diverse, urban area. A similar program was implemented in a rural, predominantly white population served by the Iowa City Veterans Affairs (VA) Health System. However, in this program, the researchers randomized patients to receive usual care, mailed educational information with a FIT test, or mailed educational materials only.[11] In the PHHS study, patients in the FIT and colonoscopy invitation group who did not respond within two weeks received a follow-up telephone phone call as a repeat invitation to participate in screening. In the Iowa City study, no follow-up phone call was conducted.

Both the Parkland and Iowa City interventions relied on existing chart data to determine patient eligibility. In the Parkland study, patients were included if they were aged 50-64 years, residents of Dallas County, and had visited one of the system’s primary care clinics in the year prior to randomization. Patients were excluded if they were up to date with CRCS, defined as having received a FIT test in the previous year, sigmoidoscopy in the past five years, or colonoscopy in the past 10 years.[14] In the Iowa City study, patients age 51-64 who had two or more primary care visits in the past 13 months and were not up to date with CRCS were included.[11] Both studies excluded patients with a known history of CRC, polyps, or inflammatory bowel disease. Adults age 65 and older were excluded in both studies.[11, 14, 15] The Iowa City VA excluded elderly adults given the likelihood that these patients may utilize non-VA services through Medicare.[11] The
PHHS study did not include adults 65 and over because all participants had Parkland Healthplus (PHP) coverage, which is not available to those who qualify for Medicare B.[16]

The results of each study are summarized in Table 3 and Table 4.[11, 14]

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Screening Participation Within 12 Months of Randomization</td>
</tr>
<tr>
<td>Mailed FIT</td>
<td>58.8% (n = 1410/2400)</td>
</tr>
<tr>
<td>Mailed Colonoscopy Invitation</td>
<td>42.4% (n = 1018/2400)</td>
</tr>
<tr>
<td>Usual Care</td>
<td>29.6% (n = 355/1199)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mailed FIT + Educational Materials</td>
<td>21% screened within 6 months</td>
</tr>
<tr>
<td>Mailed Educational Materials Only</td>
<td>6% screened within 6 months</td>
</tr>
<tr>
<td>Usual Care</td>
<td>6% screened within 6 months</td>
</tr>
</tbody>
</table>

The PHHS had a 37% higher screening rate in the mailed FIT arm than the Iowa City study for a number of possible reasons. First, the study was conducted over a period of a year rather than six months, allowing more time for participants to return completed FIT tests. Second, patients in the colonoscopy invitation arm were invited to cross over to the FIT arm if they preferred, which many did. Very few crossed over from the FIT arm to the colonoscopy arm. Third, it is possible the Polymedco OC-Auto® FIT used in the PHHS study is easier to use than the Polymedco OC-Light® FIT test. Other reasons for the differences in screening rates may be related to patient demographic differences, program promotion and delivery, educational materials used, health system differences, among other reasons. The FIT Pack program to be implemented in the Buffalo Trace ADD will be modeled after the PHHS mailed FIT kit study arm with major adaptations. Some of these adaptations are
drawn from the Iowa City study and detailed below. The complete workflow of the Fit Pack program is included in Appendix D.

The four health departments and four PrimaryPlus clinics detailed in Target Population and Need will participate in the FIT Pack program by way of a delayed intervention (DI) study design using block randomization. Two health departments and two PrimaryPlus clinics will be randomly selected to receive the early intervention (EI), while the remaining two health departments and two PrimaryPlus clinics will continue with “usual care,” or maintaining their current CRCS screening practices, for the first nine months of the implementation period. We have elected to block randomize the EI and DI groups to each comprise two health departments and two PrimaryPlus clinics to maintain homogeneity and control for possible organizational and patient population differences between PrimaryPlus clinics and health departments that may confound results.

After the first nine months of the EI period, the EI group will enter an 18-month sustainability period while the DI group participates in a 9-month intervention period followed by a 9-month sustainability period. A complete timeline of the FIT Pack Program is included in Appendix B. The selected pragmatic study design conducted at the clinic level constitutes a major adaptation to the PHHS study, which randomized patients to one of three groups and did not offer a DI to the routine care group. We have selected this study design in order to compare screening rates both between clinics in separate study arms and within clinics prior to and after the intervention to better control for any variables that may confound true differences detected between study arms.

The FIT Pack program will not include an initial invitation for colonoscopy because the health departments and PrimaryPlus clinics in the Buffalo Trace ADD cannot provide
these services; therefore patients would need a referral to the SOMC, Meadowview RMC, or another clinic with the capacity to provide colonoscopies. Therefore, colonoscopies will only be available to patients who have positive FIT tests or who contact their PCP directly for CRCS. We do not anticipate that this will negatively impact the total number of patients who are screened for CRC, because previous studies have shown that patients in underserved populations tend to prefer FIT screening rather than colonoscopy[15, 17, 18]. Furthermore, in the PHHS study, over one-third of patients in the colonoscopy outreach arm crossed over to FIT screening. [14]

An additional adaptation to the PHHS program protocol for the FIT Pack program will be the delivery of educational materials with the FIT kits during the intervention period. Patients will receive a copy of the CDC’s Screen for Life fact sheets and brochures (shown in Appendix G) in their FIT packs. The program has chosen these materials because they were included with FIT kits in the Iowa City study and are relatively low-cost additions to each FIT Pack.

Another adaptation to the Fit Pack program is the expansion of eligibility criteria to include all adults age 50-75. Adults age 65-75, who were excluded in the PHHS and Iowa City VA studies, will be included in the FIT Pack program for three reasons. First, the FIT Pack program’s goals are to reach all adults in the Buffalo Trace ADD who are overdue for CRCS, which includes adults age 50-75. Second, adults over age 65 were not included in the PHHS or Iowa City study because of health system barriers that we do not anticipate encountering in Buffalo Trace health departments or FQHCs. Third, previous studies have shown that older adults are more likely to return FIT tests than those under age 65 [19,
20], which will further broaden the reach of the FIT Pack program. A complete description of the FIT Pack program’s eligibility criteria is included in Appendix C.

The FIT Pack program will be adapted to use the patient’s existing medical coverage, where applicable, upon return of FIT test. In both the PHHS and Iowa City VA studies, medical coverage was provided by the institution rather than through outside plans such as Medicare, Medicaid, or commercial insurance. Because yearly FIT tests are covered by Medicare and Kentucky Medicaid [21], the use of insurance when applicable will result in no cost to the patient, but will reduce the financial burden of the program as a whole. Additionally, incorporating a step for billing insurance into the protocol will increase sustainability of the program moving forward, as clinic staff will gain experience with billing procedures. The invitation letter from the PHHS Fit invitation letter will be adapted to the FIT Pack program and will disclose that the program will bill insurance, if applicable. For a complete copy of the FIT Pack screening letter, see Appendix E.

Finally, the FIT Pack program will add a minor adaptation to further incentivize FIT kit return. If completed FIT kits are mailed back to clinic sites within 14 days of receipt, patients will be sent a free program T-shirt. A sample of the T-shirt is included in Appendix K. Program incentives will be subject to formative and continuous evaluation by program staff, Community Advisory Group (CAG) members and focus group participants. More information about focus group and CAG involvement can be found in the Program Planning section. A list of CAG members can be found in Appendix A.

The FIT Pack program will maintain close fidelity with the PHHS’s delivered materials in the FIT arm, including use of the Polymedco OC-Auto® FIT. The decision was made to use the same type of test because any change from the original study in brand or
type of FIT test selected may result in reduced patient acceptance of the test, increased
time commitment, or decreased ease of use.

Participant Surveys

On July 1, 2018, web-based surveys will be administered to clinic staff and
healthcare providers to assess their knowledge and awareness of CRCS guidelines. Surveys
are shown in Appendix M. The FIT Pack Liaison will email surveys with weekly reminders.
Clinic staff will be incentivized with the option of entering a drawing to win one of four
$100 Visa gift cards. During the third year of the grant period when all clinics are in the
sustainability period, the same survey (and incentives) will be released in November 2020
to establish changes in baseline clinician knowledge, awareness, and acceptance of CRCS
guidelines.

Patient Satisfaction Survey

Six months after each FIT Pack is mailed out, the FIT Pack Liaison will call patients
who were mailed a FIT (regardless of whether or not the FIT was returned to clinic) and
conduct a Patient Satisfaction Survey (shown in Appendix N.) The purpose of the survey
will be to assess existing barriers to CRCS and identify areas for continuous quality
improvement. More information about Patient Satisfaction Surveys is included in the

Performance Measures and Evaluation section.

Program Promotion

Program staff will work with establishments in the Buffalo Trace ADD to create
supportive community norms for CRCS by way of “Dress in Blue” days throughout the grant
period. Pastors at local churches who serve on the CAG (see Appendix A) will work with
church staff to coordinate “Dress in Blue” Sundays during March 2019, and church bulletins
will contain a folded copy of the CDC’s *Screen for Life* flyers. Kroger grocery stores in Kentucky have historically supported “Dress in Blue” days.[22] Program staff will work with Kroger in Maysville to coordinate a “Dress in Blue” day during each quarter of the grant period. Kroger will also host a “Dress in Blue” week during March 2019, during which Kroger staff will wear “Ask Me Why I’m Blue” stickers. Staff will be trained to explain that it is CRC Awareness Month and offer CDC *Screen for Life* flyers to customers. All “Dress in Blue” days will be discussed with the CAG and focus groups prior to implementation and reevaluated in quarterly focus group meetings.

Program staff will also work with the Kentucky Cancer Program (KCP) to rent an Incredible Colon (Figure 3) for display in frequently visited community areas. CAG and focus group members will give input on events in the Buffalo Trace ADD that are most frequented by community members, such as county fairs, back-to-school events, or church fall festivals. Two local festivals or fairs will be selected in the fall of 2018 based on focus group and CAG input and Incredible Colon availability. At least two program staff will remain with the Incredible Colon to distribute CDC *Screen for Life* flyers and provide education for Buffalo Trace ADD residents. Program staff will also offer the CDC’s Colorectal Cancer Quiz and visitors to the Incredible Colon will be invited to take the quiz for a chance to spin a prize wheel. Prizes will include $5 Visa cards, program T-shirts, program grocery totes, and program wristbands. Samples of these program items can be found in Appendix H. Prior to implementation, focus group members will review the printed copies of the CDC’s Colorectal Cancer Quiz for appropriate level of literacy and offer any suggestions for adapting the quiz to Buffalo Trace ADD.
residents. They will also be asked to provide insight on prize items and offer suggestions for improvement or ideas for different types of prize items to offer.

In March 2019, program staff will place printed copies of the CDC’s *Screen for Life* flyer and Colorectal Cancer Quiz on tables in the front of Kroger and Walmart in Mason County, the Lewis County and Fleming County Save-A-Lot stores, Thomas Grocery in Robertson County, and Lee’s Bestway IGA in Bracken County. Customers will be invited to take the quiz in-store or take the quiz home and return it to the grocery prior to March 30. A drop box will be placed on tables in the front of each store with directions for customers to deposit their quizzes with their name and contact information if they would like to be entered into a drawing for a $10 gift card to the store in which they deposited the quiz. At the end of the month, program staff will collect quizzes from each store, grade quizzes for accuracy, and randomly select one complete and accurate quiz from each site. If a site does not collect a quiz that is completely accurate, highest scores will substitute in the drawing. CAG and focus group members will review the list of participating grocery stores and offer suggestions for changing sites or adding a store based on their knowledge of which grocery stores are most popular in each county.

*Program Planning*

The grant period will start in June 2018. The first three months of the grant period (June – August 2018) will include collaboration with the Buffalo Trace DCC, area health departments, PrimaryPlus clinics, and CAG. This collaboration period will focus on how best to implement the program to meet Buffalo Trace ADD community members’ needs, program staff education and training, establishing the optimal workflow for each clinic site involved, and staff preparation for appropriate program evaluation. The first three months
of the grant period will involve training a community health worker, herein known as the FIT Pack Liaison, on program goals and objectives, program protocols, provider and staff education, and patient education. Randomization of clinics will occur in July 2018 to provide time to schedule meetings and training sessions with EI clinic staff and to ensure adequate time to compile supplies necessary based on the volume of patients we anticipate to serve at each clinic site.

The second three months of the grant period (September – November 2018) will involve FIT Pack Liaison training of EI PrimaryPlus and Health Department clinic staff on program protocol, scripts for patient phone calls, patient education, and appropriate documentation. Clinic staff will complete the CDC’s *Screening for Colorectal Cancer: Optimizing Quality* training modules[23], led by the FIT Pack Liaison, and receive continuing education (CE) during this period. Clinic staff will be expected to pass CE quizzes and complete this training yearly during the grant period. The FIT Pack Liaison will train EI clinic staff on appropriate use of REDCap for documentation of patient screening status, patient communication, and outcomes during this portion of the planning period. The EI clinic staff training conducted during the second three months of the grant period will be repeated for the DI clinics from June-August 2019 so that the period between clinic staff training and program implementation is equal for EI and DI groups.

In August 2018, the program will contract with a computer programmer with experience using both health department and PrimaryPlus electronic medical records (EMRs) to generate a master list of all patients with at least one clinic visit in the 12 months prior who are eligible for CRCS per eligibility criteria listed in Appendix C. This list will be used to compare baseline information – such as patient demographics, CRCS compliance,
and patient volume – among the different clinic sites. Each clinic will be responsible for the patients on the list generated at their own clinic site, but a program staff member will review a comprehensive list of all patients eligible for screening specifically to monitor for patient duplication. If a patient visited more than one of the participating clinics in the last year, the clinic of the patient’s home county will be assigned to that patient. If a patient visited more than one participating clinic in the last year, and both clinics are located in the patient’s home county (e.g., Fleming County Health Department and Flemingsburg PrimaryPlus), the most recently visited clinic will be assigned to that patient. The computer programmer will generate updated lists of eligible patients for program sites at the end of the planning period and quarterly during the intervention period. Patients from the master list who are no longer eligible for screening (e.g., an outside colonoscopy was documented as performed in October 2018) will be removed from the list of patients to screen during the intervention period at that time.

From June – August 2018, CAG members will also recruit community members in the targeted age range to participate in focus groups. Focus groups will give insight on community members’ perceptions of CRC, knowledge of existing processes for CRCS, impressions of FIT kits, perceived barriers to CRCS adherence, and recommendations for improving intervention materials. Focus groups will review FIT kit instructions, FIT Pack educational materials, and FIT Pack instructions for appropriate literacy levels to proactively identify issues with program accessibility. They will also give perspective on the proposed promotional events in the community to ensure that program activities are relevant to community members. All focus group members will be incentivized to
participate with a free meal and a $20 gift card for each quarterly meeting attended, further detailed in the Budget and Justification in Appendix O.

Colonoscopy Referral

Participants with positive FIT tests will receive appropriate referral to Buffalo Trace Gastroenterology in Mason County, the Meadowview RMC, or the SOMC depending on participant preference and clinic availability. This partnership will allow for health workers from the clinics’ mailing FIT kit screening program to communicate between referral clinics and patients, reducing perceived and actual barriers to follow-up care. Reaching 100% of patients with positive FIT tests is anticipated to be a major challenge to this program, which is why every FIT Pack comes with a return slip where patients are asked to list their best contact phone number and email address. An example of this can be found in Appendix F.

Sustainability

The FIT Pack program will remain sustainable following the 3-year grant period. Because most commercial insurance plans, Medicare, and Medicaid, cover the cost of at-home fecal blood tests, clinic sites will be able to afford to continue screening patients with healthcare coverage. Furthermore, because each of the eight participating clinic sites already offers at-home fecal blood tests on a sliding scale to patients without healthcare coverage, we do not anticipate that they will lose the funding to cover services to these patients at the conclusion of the grant period.

Clinic sites will also further develop the capacity to generate lists of patients due for CRCS through collaboration with the program’s contracted computer programmer. The programmer will visit clinic sites quarterly during their respective intervention periods to
assist with the generation of eligible patient lists. During the sustainability period, clinics will be expected to generate their own patient lists to continue CRCS with some oversight from FIT Pack Liaisons.

Finally, the program will sustain itself through strengthened partnerships with colonoscopy referral sites in the area. Because the eight primary care clinic sites will be responsible for following up on patients with positive FITs who are referred for colonoscopy during the sustainability period, we anticipate that they will improve communication with referral sites so that patient medical information remains updated in clinic systems, and resources are not wasted on outreach to patients who are up-to-date with CRCS guidelines.

**Performance Measures and Evaluation**

FIT Pack program staff will be responsible for collecting and recording implementation and outcomes measures at baseline and periodically during the grant period. The contracted computer programmer will be responsible for generating baseline lists of active patients age 50-75 from the EMRs at each clinic site and generating new lists every quarter during the intervention period. The programmer will also include patient demographics, financial information, clinic site, and date of last clinic visit with each list. FIT Pack Liaisons will be charged with recording measures and maintaining an up-to-date list of all measures, which will be sent to the Project Coordinator every four weeks. The Project Coordinator will maintain records of these measures and share data with grant funders on a quarterly basis. The listed program database will consist of a shared REDcap project. Clinic staff will receive REDCap data entry training during the first six months of the program (as detailed
in the **Program Approach**) and will receive ongoing “refresher” courses quarterly during the intervention period. FIT Pack Liaisons will be responsible for visiting clinic sites biweekly during the intervention period to monitor for program fidelity and appropriate documentation and patient follow-up.

*Implementation Evaluation*

To ensure that the FIT Pack program is implemented as intended, implementation measures will be collected on a monthly basis and analyzed each quarter. Implementation measures are listed in [Table 6](#). FIT Pack Liaisons will be responsible for collecting these data each month and sending a report to the Project Coordinator. The Project Coordinator will then be responsible for quarterly analysis and reporting to the Program Director, project funders, and biostatistician for statistical analysis.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of clinic staff members at the 8 primary care sites who have received CE for the CDC <em>Screening for Colorectal Cancer: Optimizing Quality</em> by 12/1/18</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Clinic staff CE scores</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Baseline: No. of clinic staff members at each site who participated in the knowledge and awareness survey</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Post-intervention: No. of clinic staff members at each site who participated in knowledge and awareness survey</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients eligible for CRCS (per program protocol) at each site who were randomized to receive FIT and were mailed a FIT</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients mailed a FIT who returned the test within 14 days</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients mailed a FIT who required 1 reminder phone call after 14 days</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients who returned FIT within 14 days of 1st reminder call</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients mailed a FIT who required 2 reminder phone calls to complete FIT</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients who returned FIT within 14 days of 2nd reminder call</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients mailed a FIT who required 3 reminder phone calls</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients who returned FIT within 14 days of 3rd reminder call</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of valid FITs returned to clinic</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of invalid FITs returned to clinic</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Description</td>
<td>Database</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>No. of patients who returned invalid FITs and were contacted to re-screen</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients who returned invalid FITs and were mailed a new FIT test</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients who returned invalid FITs and re-screened within 14 days</td>
<td>REDCap database</td>
</tr>
<tr>
<td>of receipt of new FIT</td>
<td></td>
</tr>
<tr>
<td>No. of patients who initially returned invalid FITs and returned valid FITs</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients with normal FIT results who were mailed the Negative FIT</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Letter within 14 days</td>
<td></td>
</tr>
<tr>
<td>No. of patients with abnormal FIT results who were contacted with positive</td>
<td>REDCap database</td>
</tr>
<tr>
<td>results within 14 days</td>
<td></td>
</tr>
<tr>
<td>No. of patients with abnormal FIT who were referred for colonoscopy</td>
<td>Clinic EMR, referral site EMR, REDCap database</td>
</tr>
<tr>
<td>No. of patients with abnormal FIT who scheduled colonoscopy</td>
<td>Referral site EMR, REDCap database</td>
</tr>
<tr>
<td>No. of patients with abnormal FIT results who received colonoscopy within</td>
<td>Referral site EMR, REDCap database</td>
</tr>
<tr>
<td>6 months of FIT kit mail-out date</td>
<td></td>
</tr>
<tr>
<td>No. of patients who were called to participate in a Patient Satisfaction</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Survey</td>
<td></td>
</tr>
<tr>
<td>No. of patients who participated in the Patient Satisfaction Survey</td>
<td>REDCap database</td>
</tr>
</tbody>
</table>

Implementation evaluation will allow project staff to determine if the current program protocol is sufficient for resulting in the desired outcomes and address any necessary changes to program implementation. For example, if more than 75% of patients require telephone reminder calls to complete the FIT, program staff may implement a protocol to call patients earlier than 14 days from postmark.

**Outcomes Evaluation**

Project staff will be responsible for collecting outcomes measures to determine that the program accomplishes its goals and objectives. Outcomes measures are listed in Table 7. As with the implementation outcomes, FIT Pack Liaisons will be responsible for collecting these data each month to send to the Project Coordinator. The Project Coordinator will then report data to the Program Director, funders, and the biostatistician quarterly.
Table 7. FIT Pack Program Outcomes Evaluation Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proportion of Patients Screened with Mailed FIT</strong></td>
<td></td>
</tr>
<tr>
<td>At baseline: No. of patients age 50-75 eligible for CRCS who have had a clinic appointment at one of the 8 sites from June 2017-May 2018</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td>At baseline: No. of patients age 50-75 who have had a clinic appt. at one of the 8 sites from June 2017-May 2018 and are up-to-date with CRC</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td>No. of eligible patients screened for CRCS at one of the EI sites from 12/1/18 – 8/31/19</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td>No. of eligible patients screened for CRCS at one of the DI sites from 12/1/18 – 8/31/19</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td>Intervention period: No. of patients mailed FIT test</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Intervention period: No. of patients who returned FIT test during grant period</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Intervention period: No. of patients who returned valid FIT tests</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Intervention period: No. of patients who returned invalid FIT tests and were contacted to complete another FIT test</td>
<td>REDCap database</td>
</tr>
<tr>
<td>Intervention period: No. of patients who returned invalid FIT tests and complete another FIT test</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients whose FITs were normal</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients whose FITs were abnormal</td>
<td>REDCap database</td>
</tr>
<tr>
<td>No. of patients with abnormal FITs who were referred for colonoscopy</td>
<td>Clinic EMR, referral site EMR, REDCap database</td>
</tr>
<tr>
<td>No. of patients with abnormal FIT who received colonoscopy</td>
<td>Referral site EMR</td>
</tr>
<tr>
<td>No. of patients mailed a FIT who contacted the clinic to schedule colonoscopy instead</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td><strong>Patient Satisfaction</strong></td>
<td></td>
</tr>
<tr>
<td>Patient satisfaction with FIT Pack program</td>
<td>Patient satisfaction surveys</td>
</tr>
<tr>
<td>Sustainability period: No. of patients mailed FIT test</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td>Sustainability period: No. of patients who returned FIT test during grant period</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td>Sustainability period: No. of patients who returned valid FIT tests</td>
<td>Clinic EMR</td>
</tr>
<tr>
<td><strong>Clinic Staff Knowledge and Attitudes of CRCS</strong></td>
<td></td>
</tr>
<tr>
<td>At baseline: Clinician knowledge questionnaire results</td>
<td>Clinician survey data in REDCap database</td>
</tr>
<tr>
<td>Post-intervention: Clinician knowledge questionnaire results</td>
<td>Clinician survey data in REDCap database</td>
</tr>
</tbody>
</table>

To assess the primary intervention, total number of patients screened, FIT packs returned within one year will qualify for a screening event, regardless of whether or not results are valid. Clinic staff will be responsible for recording returned FIT packs in REDCap, which will then be accessible to FIT Pack liaisons. Baseline CRCS rates will be
compared between clinics randomized to the EI and DI, as detailed in Table 7. On September 1, 2019, CRCS rates will again be compared between EI and DI groups. Change in screening rates from baseline will be compared between EI and DI clinics. Similar comparisons will be made on June 1, 2020, at the conclusion of the DI period and halfway through the sustainability phase of the EI period. The sustainability of the project will be evaluated by collecting CRCS rates every nine months for each clinic in the sustainability period. CRCS rates during the sustainability period will then be compared to CRCS rates collected post-implementation.

For clinic staff awareness outcomes, project staff will administer surveys to clinicians and staff members at the eight participating sites to ascertain clinician knowledge of CRCS and their perceptions of patient knowledge, attitudes, and barriers to CRCS. The first survey will be administered during July 2018 prior to clinician and staff training sessions with FIT Pack liaisons. The survey is adapted from an existing instrument that has been tested in community health centers in previous studies.[24] Additional questions about USPSTF screening recommendations have been added to ascertain clinician and staff knowledge and awareness of current guidelines.[6] The survey will be administered via REDCap and delivered through email, though project staff will collaborate with clinic administrators to determine if paper surveys would be preferred. Clinic staff will receive email reminders once weekly to complete the survey before it closes. Program staff will not require that clinic employees complete surveys, but they will be incentivized by the opportunity to enter into a drawing to win a $100 Visa gift card.

Patient satisfaction will be evaluated by way of the Patient Satisfaction Survey in Appendix N. FIT Pack Liaisons will be responsible for conducting these surveys over the
phone. The Project Coordinator will analyze survey responses on a quarterly basis to perform continuous quality improvement.

**Capacity and Experience of Applicant Organization**

*The Buffalo Trace Cancer Coalition (BTCC)*

The BTCC is made up of the Fleming, Lewis, Bracken, and Buffalo Trace District Health Departments and includes the existing Fleming County Cancer Coalition. The mission statement of the BTCC is to lead its community members to reduce their risk of cancer and its related complications. The vision of the BTCC is a healthy, empowered community. The mission and vision of the BTCC are derived from the mission and vision of the BTDHD, which seeks to improve the health of community members by increasing their awareness, self-efficacy, and access to care. The BTDHD also represents its values using the acronym CARE [25]:

- Confidentiality: The Health Department will ensure confidentiality of all patients.
- Accountability: The Health Department will hold itself accountable for practicing with integrity and fairness.
- Respect: The Health Department will treat all patients and community members with respect at all times.
- Equality: The Health Department will treat all patients and community members equally regardless of race, ethnicity, culture, language, or socioeconomic status.

The BTCC will adopt the values of the BTDHD for this CRCS program to fulfill its mission and vision. The proposed CRCS program aligns with the BTCC’s mission and vision because its goals include not only reducing CRC morbidity and mortality through early detection
and screening but also providing education and resources to community members to empower them to take control of their own health. In the short term, community members are projected to be more informed about USPSTF CRCS recommendations and undergo early detection and screening as a result of education and resources provided by this screening program. In the long-term, community members are expected live longer as a result of early detection and screening. Incidence of CRC will decrease over time as a result of early polyp removal in those with positive FIT tests, and incidence of invasive CRC will decrease as a result of CRC detection in localized stages. Finally, CRC mortality will decrease as a result of a reduction in detection of CRC in advanced stages and a reduction in the need for multiple cycles of chemotherapy.

The BTCC is comprised of organizations with experience in implementing community-wide health campaigns. In 2017, the Bracken County Health Department and PrimaryPlus in Bracken County partnered to offer qualifying patients free OC-Light® S FIT Polymedco tests. The Bracken County Health Department also spearheaded a CRC awareness campaign in March 2017 in which all employees wore blue and encouraged community members to wear blue. These existing initiatives demonstrate that the Bracken County Health Department and PrimaryPlus are equipped with competent staff who can educate patients on the use of the Polymedco OC-Light® S FIT test and who are willing and able to launch a CRC awareness campaign.

Outside of CRCS efforts, each health department involved in the BTCC has experience implementing awareness campaigns and community-wide interventions. The BTDHD hosts multi-week programs that use a team-based approach to promote healthy lifestyles among community members.
The PrimaryPlus clinics in Bracken, Fleming, Lewis, and Mason Counties have served as providers of primary-level healthcare for several years, operating a team-based approach to preventive care and chronic disease management through their trademarked WeCare® program. The National Committee for Quality Assurance (NCQA) has recognized the Bracken and Mason County PrimaryPlus clinics as Level III Patient Centered Medical Homes (PCMHs). The NCQA standards focus on the use of accessible, patient-centered care and emphasize effective patient communication and patient and family involvement in all medical decisions.

The PrimaryPlus clinics involved with this CRCS program are experienced in the implementation of evidence-based public health programs. For example, PrimaryPlus clinics offer a Lifestyle Enhancement Activity Program (LEAP®) to businesses and other community members to encourage healthy behaviors such as smoking cessation, regular physical examinations, and other types of regular health screening. The program also offers extended hours until 6:00pm on certain weekdays, indicating that the PrimaryPlus clinics involved with the CRCS program have the capacity to provide accessible care to the target population.

The SOMC serving Lewis County offers community-wide events. The majority of the events are free classes focused on chronic disease self-management and tobacco cessation; however, through the Hands of Hope grant, the medical center offers free breast clinical exams and same-day imaging for women with breast abnormalities in the community. The SOMC also offers access to NCI-sponsored clinical trials through the Columbus Community Oncology Program (CCOP) and may serve as a referral site for patients with confirmed CRC after colonoscopy.[26] Finally, the SOMC conducts yearly community-wide needs
assessments and creates implementation plans to provide valuable, well-planned services for their patients through an efficient use of resources.

**Partnerships and Collaboration**

Collaboration with community clinics and other stakeholders is paramount for the success of the FIT Pack program. Collaboration will ensure the intervention is both relevant and appropriately delivered to community members in need. Furthermore, partnerships will ensure that healthcare resources are used efficiently and provide partners with the capacity to continue evidence-based screening and education programs once this specific intervention concludes.

*Local Clinics*

The primary stakeholders involved with the mailed FIT kit CRCS program are the clinics with access to patient medical records, contact information, resources to educate patients on the appropriate use of FIT kits, and clinic staff who are capable of communicating results with patients during follow-up. Thus, the Health Departments and PrimaryPlus clinics will be the primary partners collaborating on this project. In the 2017 partnership between PrimaryPlus and the Bracken County Health Department, the Health Department was responsible for community outreach, directing PrimaryPlus patients to PrimaryPlus clinics for continuity of care, and directly providing FIT kits to all community members who were not existing PrimaryPlus patients. [27] Using this established model, the Fleming, Lewis, Bracken, and Buffalo Trace District Health Departments will generate a list of patients age 50-75 without a charted history of CRCS per USPSTF recommendations. Through collaboration with PrimaryPlus, the Health Departments will have access to
PrimaryPlus patient charts to ascertain whether patients received adequate screening through PrimaryPlus clinics prior to reaching out via telephone. Collaborating with PrimaryPlus, which likely shares some patients with the Health Departments, will allow for a more efficient use of time and project resources so that phone calls are not duplicated among clinics and FIT tests are not mailed to patients who are up-to-date on CRCS per USPSTF guidelines.

_Gastroenterology Clinics_

As mentioned in the **Program Approach**, patients with positive FITs will receive appropriate referral to Buffalo Trace Gastroenterology in Mason County, the Meadowview RMC, or the SOMC depending on participant preference and clinic availability. This partnership will allow for continuity of care for patients who require additional follow-up. It will also strengthen the existing relationship between the eight primary care clinics in the FIT Pack Program and the colonoscopy referral sites in the area.

**Program Management**

Given that this project will operate out of local clinics and health departments within the Buffalo Trace ADD, the Program Director will have a Master or Doctor of Public Health degree, Master or Doctor of Health Administration degree, or have at least five years of experience in an administrative position within a health system. The Project Director will supervise the work of all project staff during program implementation. The Project Director will also have established connections locally to serve as the liaison between project staff, the CAG, and clinic partners and will serve to facilitate quarterly meetings among project staff and partners. Finally, the Project Director will be, at a minimum, a
member of the American Public Health Association (APHA) and Kentucky Public Health Association (KPHA) and will attend national and state meetings to present program abstracts and gather information for program development. The Program Director will also attend one other national meeting such as the biannual CDC Cancer Conference or National Colorectal Cancer Roundtable based on its relevance to this program, selected at his or her own discretion.

The Project Coordinator will manage day-to-day implementation of this program and serve as the direct supervisor to the FIT Pack Liaison and the Master of Public Health (MPH) student. The Project Coordinator should have an advanced, post-graduate degree in a health-related field (e.g., MPH) and previous experience with management of large projects. Program implementation will require that the Project Coordinator oversee: the computer programmer’s identification of eligible community members using clinic software, communication with community participants, management of materials as they are received and shipped to eligible participants, redirection of returned kits for appropriate interpretation, data collection, pre- and post-intervention survey development and distribution for clinic staff, and completion of all reporting prior to the necessary deadlines. The Project Coordinator will also be responsible for compiling annual reports on CRC national and state-level statistics, screening data, relevant publications, and quarterly reports on program progress. These reports will be disseminated to clinic partners and members of the CAG at quarterly program development and evaluation meetings. Finally, the Project Coordinator will also attend KPHA meetings in addition to one other national conference with the Program Director, and will be primarily responsible for abstract presentation at these meetings.
Additional staff will include a community health worker known as the FIT Pack Liaison whose primary responsibilities will be: to visit clinics, discuss CRCS guidelines with providers, identify information for patient handouts and mailed leaflets, instruct clinic staff on appropriate program protocol, contact patients for follow-up Patient Satisfaction Surveys, work with the Project Coordinator to disseminate clinician surveys, and provide general oversight and support for clinical staff when questions or issues arise. Each of the eight sites involved with the CRCS intervention will have a nurse manager on staff whose role will be to work with the computer programmer to help identify patients in the clinic eligible for screening, determine screening status, and flag those who have not been screened for CRC to be mailed a FIT test.

Finally, the program will hire a graduate student to aid with mailing FIT tests with the appropriate information, inputting data, and helping the FIT Pack Liaison conduct Patient Satisfaction Surveys. The graduate student will also contribute to writing conference abstract(s) with final approval by the Project Coordinator and Program Director and will assist with drafting the final manuscript(s) if he or she is still involved with the project at its conclusion. The student will also be present at quarterly meetings and encouraged to attend KPHA and national meetings to present study findings.
Citations


# Appendix A. FIT Pack Community Advisory Group (CAG)

<table>
<thead>
<tr>
<th>CAG Member</th>
<th>Description</th>
<th>Anticipated Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trina Winter</td>
<td>Buffalo Trace District Cancer Council&lt;br&gt;Regional Cancer Control Specialist</td>
<td>Provide information on successes and failures of previous prevention programs, give perspective on community health needs and perceived barriers to care</td>
</tr>
<tr>
<td>Donald Weller, MD</td>
<td>Gastroenterologist at Buffalo Trace Gastroenterology</td>
<td>Contribute to program promotion in the community, provide insight on patient experiences with CRCS, give expert opinion on quality and accuracy of patient and provider educational materials</td>
</tr>
<tr>
<td>Deborah Weber, CSW</td>
<td>Maysville PrimaryPlus Licensed Clinical Social Worker</td>
<td>Give perspective on community health needs and perceived barriers to care, contribute perspective of PrimaryPlus clinic workflow, existing resources for program contribution, and suggestions for incorporating program goals into PrimaryPlus clinic workflow</td>
</tr>
<tr>
<td>Fleming County Cancer Coalition Representative</td>
<td>Local cancer coalition focused on community-wide education and prevention</td>
<td>Give perspective on community health needs and perceived barriers to care, provide information on successes and failures of previous prevention programs, and promote the program to Fleming County citizens</td>
</tr>
<tr>
<td>Joseph Koch, CPPS</td>
<td>CEO of Meadowview Regional Medical Center</td>
<td></td>
</tr>
<tr>
<td>Jennifer Markley, RN</td>
<td>Bracken County Health Department Employee Involved with 2017 Health Department-PrimaryPlus Partnership to increase CRCS</td>
<td>Advise program on successes and challenges of health department and PrimaryPlus partnership, give perspective on community health needs and perceived barriers to care, and contribute suggestions for incorporating program goals into Health Department workflow</td>
</tr>
<tr>
<td>Tom Cox</td>
<td>Preacher at Vanceburg Christian Church in Lewis County</td>
<td>Give perspective on community health needs and perceived barriers to care, aid with promotion of program in the community</td>
</tr>
<tr>
<td>Shane Roberson</td>
<td>Senior Minister at Maysville Baptist Church in Mason County</td>
<td>Give perspective on community health needs and perceived barriers to care, aid with promotion of program in the community</td>
</tr>
<tr>
<td>Cletus Rumpfeather</td>
<td>Teller at Community Trust Bank in Fleming County</td>
<td>Give perspective on community health needs and perceived barriers to care</td>
</tr>
<tr>
<td>Judy Planck</td>
<td>Licking Valley</td>
<td>Provide perspective on community health</td>
</tr>
<tr>
<td>Community Action Program Executive Director</td>
<td>needs and perceived barriers to care, connect program to neediest members of the Buffalo Trace ADD</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Phyllis Ritchie</td>
<td>President of Fleming County Cancer Club</td>
<td>Provide perspective from local CRC survivors and family members, give perspective on community health needs and perceived barriers to care</td>
</tr>
</tbody>
</table>
Appendix B. Program Timeline

FIT Pack Program Timeline
6/1/2018 - 5/31/2021

- Program Planning
  6/1/2018 - 11/30/2018

- Early Intervention (Clinics 1-4)
  12/1/2018 - 8/31/2019

- Usual Care (Clinics 5-9)
  12/1/2018 - 8/31/2019

- Sustainability (Clinics 1-4)

- Delayed Intervention (Clinics 5-8)
  9/1/2019 - 5/31/2020

- Sustainability (Clinics 5-8)
  6/1/2020 - 2/28/2021

- Evaluation Period
  3/1/2021 - 5/31/2021
Appendix C. Patient FIT Pack Program Eligibility

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 50-75 years at time of chart review</td>
<td></td>
</tr>
<tr>
<td>Resident of Buffalo Trace ADD</td>
<td></td>
</tr>
<tr>
<td>Address and phone number in EHR</td>
<td></td>
</tr>
<tr>
<td>Clinic visit at one of the 8 participating clinics in the last 12 months</td>
<td></td>
</tr>
<tr>
<td>No documented colonoscopy in last 10 years, sigmoidoscopy or CT colonography in last 5 years, or stool-based test in the last 1 year</td>
<td></td>
</tr>
<tr>
<td>No documented history of rectal bleeding, inflammatory bowel disease, colorectal polyps, colectomy, or CRC</td>
<td></td>
</tr>
<tr>
<td>No documented incapacity to participate in CRCS, as judged by program providers and staff (e.g. debilitating mental condition)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix D. FIT Pack Program Workflow

1. Clinics Randomized

2. Eligible patients identified

3. Mail FIT Pack

   Returned by day 14

   4a. Send to lab

   5a. Result documentation & PCP notification

   6a. PCP to document patient notification & referral (if necessary)

   Not returned by day 14

   4b. Follow-up phone call invitation to screen

      No answer

      5b. Leave VM (per script) if answering machine

      Document

      No return call within 3 business days

      Return to Step 4b. Repeat 2 more times.

      Document “nonresponder” after 3 attempts

      Return call within 3 business days

      Follow algorithm for answered calls in Step 4b

      Declines screening

      Agrees to screen**
Appendix E. FIT Pack Invitation to Screen Letter and Return Form

<Date>
<Patient First, Last Name>
<Patient Address>
<Patient City, State, Zip>

Dear <Prefix, Patient First, Last Name>:

Here are two things your doctors at <Clinic Site> would like you to know:

1) Your risk of colorectal cancer goes up as you get older.
2) Screening tests can find colon problems early, so problems can be treated before they get serious.

That’s why we have mailed you this FREE stool blood test kit. This test can find small amounts of hidden blood in your stool or bowel movement that can be a sign of cancer.

Research has shown that this simple test can have big benefits. If everyone age 50 and older did this test every year, there would be many fewer deaths from colorectal cancer.

Please use the kit and do the test as soon as possible. The kit includes pictures and easy-to-follow directions. You do it in the privacy of your bathroom. After a bowel movement, use the stick in the kit to dab a small amount of stool into the collection tube. Write the date on the tube, put the tube in the bag, and mail it back with the checklist on the next page using the pre-paid return envelope.

If you return by <Date>, we will send you a FREE T-shirt!

If any blood is found, we will recommend some other tests. If no blood is found, you repeat the test after one year.

If you have medical coverage, such as commercial insurance, Medicare, or Medicaid, we will bill them when you return your test. This will be at NO CHARGE to you. If you do not have medical coverage, the test will still be FREE to you.

Please call <Community Health Worker> at <Phone Number> if you have any questions or concerns.

Sincerely,
<br>Provider Signature
<br>Provider Prefix, Provider First, Last Name
CHECKLIST

When you do the blood stool test, please fill out your information on this piece of paper and include it in the pre-paid return envelope with your test.

Things to include in pre-paid return envelope:

☐ This form with your signature and best phone number
  OPTIONAL: Include your T-shirt size below for a FREE T-shirt (pictured)
☐ Your blood stool sample in the tube provided

T-shirt size for a FREE T-shirt (not required):

☐ S
☐ M
☐ L
☐ XL
☐ XXL
☐ XXXL

Please call [FIT PACK LIAISON] at [PHONE NUMBER] if you have any questions or concerns.

Signature: ____________________________________________

Phone number (XXX-XXX-XXXX) to call you with your results: ________________

FREE T-shirt if you return the stool sample and this completed form by [DATE]!
Package Insert for Personal Use Kit  
Read all directions carefully before sample collection.  
Test results may be invalid if test is not performed properly.  
Samples will not be processed by the lab if the date is not written on the tube.

Sample Collection  
1. Write the date of collection on the tube.

2. Place the folded collection paper inside the toilet bowl on top of the water.

3. Deposit stool sample on top of collection paper.

4. Open green top by twisting and lifting.

5. Scrape the surface of the stool sample with the sample stick  
   before paper sinks and stool sample touches water.
   
   Cover the grooved portion of the sample stick completely with stool sample.

6. Put sample probe into tube and snap green top on tightly.  
   Do not open again.

7. Flush. Collection paper is biodegradable and will not harm septic systems.

8. Wrap the tube with the absorbent paper, and place in the plastic bag.

9. Put bag with sample into provided return envelope.

10. Peel tape, seal, and mail to <<SITE>> Lab in the prepaid envelope today.

Appendix F. Instructions for Polymedco OC-Auto® FIT test, Included in FIT Pack
Appendix G. CDC Screen for Life Flyer

**What Is Colorectal Cancer?**
Colorectal cancer is cancer that occurs in the colon or rectum. Sometimes it is called colon cancer. The colon is the large intestine or large bowel. The rectum is the passageway that connects the colon to the anus.

**Screening Saves Lives**
Colorectal cancer is the second leading cancer killer in the United States, but it doesn’t have to be. If you are 50 or older, getting a colorectal cancer screening test could save your life. Here’s how:
- Colorectal cancer usually starts from precancerous polyps in the colon or rectum. A polyp is a growth that shouldn’t be there.
- Over time, some polyps can turn into cancer.
- Screening tests can find precancerous polyps, so they can be removed before they turn into cancer.
- Screening tests also can find colorectal cancer early, when treatment works best.

**Who Gets Colorectal Cancer?**
- Both men and women can get it.
- It is most often found in people 50 or older.
- The risk increases with age.

**Are You at Increased Risk?**
Your risk for colorectal cancer may be higher than average if:
- You or a close relative have had colorectal polyps or colorectal cancer.
- You have inflammatory bowel disease, Crohn’s disease, or ulcerative colitis.
- You have a genetic syndrome such as familial adenomatous polyposis (FAP) or hereditary nonpolyposis colorectal cancer.

People at increased risk for colorectal cancer may need earlier or more frequent tests than other people. Talk to your doctor about when to begin screening, which test is right for you, and how often you should be tested.
Colorectal Cancer Can Start With No Symptoms
Precancerous polyps and early-stage colorectal cancer don’t always cause symptoms, especially at first. This means that someone could have polyps or colorectal cancer and not know it. That is why having a screening test is so important.

What Are the Symptoms?
Some people with colorectal polyps or colorectal cancer do have symptoms. They may include:
• Blood in or on your stool (bowel movement).
• Stomach pain, aches, or cramps that don’t go away.
• Losing weight and you don’t know why.
If you have any of these symptoms, talk to your doctor. They may be caused by something other than cancer. However, the only way to know is to see your doctor.

Types of Screening Tests
The U.S. Preventive Services Task Force recommends that adults aged 50–75 be screened for colorectal cancer. The decision to be screened after age 75 should be made on an individual basis. If you are aged 76–85, ask your doctor if you should be screened.
Several different screening tests can be used to find polyps or colorectal cancer. They include:

Stool Tests
Guaiac-based Fecal Occult Blood Test (gFOBT): uses the chemical guaiac to detect blood in stool. At home you use a stick or brush to obtain a small amount of stool. You return the test to the doctor or a lab, where stool samples are checked for blood.
Fecal Immunochemical Test (FIT): uses antibodies to detect blood in the stool. You receive a test kit from your health care provider. This test is done the same way as gFOBT.
FIT-DNA Test (or Stool DNA test): combines the FIT with a test to detect altered DNA in stool. You collect an entire bowel movement and send it to a lab to be checked for cancer cells.
How Often: gFOBT Once a year. FIT Once a year. FIT-DNA once every one or three years.

Flexible Sigmoidoscopy
For this test, the doctor puts a short, thin, flexible, lighted tube into your rectum. The doctor checks for polyps or cancer inside the rectum and lower third of the colon.
How Often: Every five years, or every 10 years with a FIT every year.

Colonoscopy
Similar to flexible sigmoidoscopy, except the doctor uses a longer, thin, flexible, lighted tube to check for polyps or cancer inside the rectum and the entire colon. During the test, the doctor can find and remove most polyps and some cancers. Colonoscopy also is used as a follow-up test if anything unusual is found during one of the other screening tests.
How Often: Every 10 years.

CT Colonography (Virtual Colonoscopy)
Computed tomography (CT) colonography, also called a virtual colonoscopy, uses X-rays and computers to produce images of the entire colon. The images are displayed on a computer screen for the doctor to analyze.
How Often: Every five years.

Which Test is Right for You?
There is no single “best test” for any person. Each test has advantages and disadvantages. Talk to your doctor about which test or tests are right for you and how often you should be screened.

Free or Low-Cost Screening
Colorectal cancer screening tests may be covered by your health insurance policy without a deductible or co-pay. Where feasible, CDC’s Colorectal Cancer Control Program grantees provides free or low-cost screenings to eligible men and women. To find out more visit www.cdc.gov/cancer/ccrp/contact.htm.

The Bottom Line
If you’re 50 or older, talk with your doctor about getting screened. For more information, visit www.cdc.gov/screenforlife or call 1-800-CDC-INFO (1-800-232-4636). For TTY, call 1-888-232-6348.
## Appendix H. Follow-Up Phone Call Script

<table>
<thead>
<tr>
<th>STEP</th>
<th>SCRIPT</th>
<th>RESULT</th>
<th>NEXT STEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Record which patient and what number you will be dialing.</td>
<td></td>
<td>To 1</td>
</tr>
<tr>
<td>1</td>
<td>Dial &lt;NUMDIAL&gt; and wait for an answer. Then click the button below indicating how the call was answered...</td>
<td>No Answer</td>
<td>Record “no answer” and time</td>
</tr>
<tr>
<td></td>
<td>Busy</td>
<td>Record “busy” and time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Person</td>
<td>To 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Answering machine</td>
<td>To 3</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Hello, this is &lt;NAME&gt; and I am calling on behalf of &lt;SITE&gt;. Is &lt;PREFIX&gt; &lt;FN&gt; &lt;LN&gt; available?</td>
<td>Available</td>
<td>To 8</td>
</tr>
<tr>
<td></td>
<td>Not available</td>
<td>To 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not at this number</td>
<td>To 6</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Hello this message is for &lt;PREFIX&gt; &lt;FN&gt;&lt;LN&gt;. My name is &lt;NAME&gt; and I am calling about the letter you received in the mail inviting you to complete a FREE stool blood test - one of the screening tests for colorectal cancer. If you would like to call us back, you can do so at: &lt;NUM&gt;. Thank you, goodbye.</td>
<td>END CALL</td>
<td>Record date/time.</td>
</tr>
<tr>
<td>4</td>
<td>Is this the best phone number to reach &lt;HERHIM&gt;?</td>
<td>Yes</td>
<td>To 5</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>To 7</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>When would be a convenient time to reach &lt;HIM/HER&gt;? [Record time] Thank you very much. Have a good &lt;DAY/EVENING&gt;.</td>
<td>END CALL</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Am I calling &lt;NUMDIAL&gt;?</td>
<td>Yes, but not best number</td>
<td>To 7</td>
</tr>
<tr>
<td></td>
<td>Yes, wrong number</td>
<td>Remove number from EHR, record “wrong number,” attempt other numbers if applicable. If not applicable, record date/time of call attempt.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Misdialed</td>
<td>To 1</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>What is the best phone number to reach &lt;HIM/HER&gt;? [Record number] Thank you so much for your time. Have a good &lt;DAY/EVENING&gt;.</td>
<td>END CALL</td>
<td>Record correct number in EHR and REDCap; return to 1.</td>
</tr>
<tr>
<td>8</td>
<td>&lt;PREFIX&gt; &lt;LN&gt;, I work with &lt;SITE&gt; and we are inviting patients to complete a FREE stool blood test- one of the screening tests for colorectal cancer. Did you receive the invitation and test in the mail?</td>
<td>Yes</td>
<td>To 12</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>To 9</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Okay, we can send a new invitation if your address has changed. We have the following address on file: &lt;ADDRESS&gt; Is this your correct address? [If no, record new address]</td>
<td>Yes</td>
<td>To 10</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>To 10</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Is it okay if I go ahead and let you know what is in the letter?</td>
<td>Yes</td>
<td>To 11</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>To 16</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maybe</td>
<td>To 13</td>
<td></td>
</tr>
</tbody>
</table>
The letter says:
Here are two things your doctors at <SITE> want you to know:

• First, your risk of getting colorectal cancer is going up as you get older.
• Second, screening tests can find colon problems early, so they can be treated before they get serious.

That's why we have mailed you this FREE stool blood test kit. This test can find small amounts of hidden blood in your stool or bowel movement that can be a sign of cancer. Research has shown that this simple test can have big benefits. If everyone age 50 and older did this test every year, there would be many fewer deaths from colorectal cancer.

Please use the kit and do the test as soon as possible. The kit includes pictures and easy-to-follow directions. You do it in the privacy of your bathroom. After a bowel movement, use the stick in the kit to dab a small amount of stool into the collection tube. Write the date on the tube, put the tube in the bag, and mail it back to the <SITE> Lab using the pre-paid return envelope.

If any blood is found, we will recommend some other tests. If no blood is found, you repeat the test after one year.

Would you like to take advantage of this free screening opportunity? Yes To 15

Okay. Please be sure to do it in the next day or two, and mail it in. The kit includes pictures and easy-to-follow directions. Would it be helpful to go over the sample collection instructions step by step? Yes To 17

Thank you so much for your time. Have a good <DAY/EVENING>. END CALL.
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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</thead>
</table>
| 17 | 1. Write the date of collection on the tube. Samples will not be processed by the lab if the date is not written on the tube.  
2. Place the folded collection paper inside the toilet bowl on top of the water.  
3. Deposit stool sample on top of collection paper.  
4. Open green top by twisting and lifting.  
5. Scrape the surface of the stool sample with the sample stick before paper sinks and stool sample touches water. Cover the grooved portion of the sample stick completely with stool sample.  
6. Put sample probe into tube and snap green top on tightly. Do not open again.  
7. Flush. Collection paper is biodegradable and will not harm septic systems.  
8. Wrap the tube with the absorbent paper, and place in the plastic bag.  
9. Put bag with sample into provided return envelope.  
10. Peel tape, seal, and mail to <<SITE>> Lab in the prepaid envelope today. | To 18 |
| 18 | If you have any questions, please call <NUMBER>. Thank you for your time, and have a good <DAY/EVENING>. | END CALL. Record date/time and patient confirmation. |
Appendix I. Negative FIT Letter

<DATE>
<FN>> <SLN>
<ADDRESS>
<CITY>>, <ST> <ZIP>

Dear <PREFIX>. <FN> <SUBJECTLN>,

Thank you for participating in the <SITE> colorectal cancer screening program. We are pleased to report that your recent stool test was normal. It showed no evidence of blood in your stool sample.

You should repeat this test every year. It is important to find colon problems early so they can be treated before they get serious. If everyone age 50 to 75 did this test every year, there would be many fewer deaths from colorectal cancer.

A copy of your results is with your doctor at <SITE.>

If you have questions about your result or colorectal cancer screening, please call <NUMBER>. Thank you for helping us take care of you.

Sincerely,

<PROVIDER SIGNATURE>
<PROVIDER PREFIX, PROVIDER FIRST, LAST NAME>
Appendix J. Positive FIT Letter

Dear <PREFIX>. <FN> <SUBJECTLN>,

Thank you for participating in the <SITE> colorectal cancer screening program. Your recent stool test was abnormal. There was evidence of blood in your stool sample. Blood in the stool may be found because of hemorrhoids, small growths in your colon called polyps, or may be from cancer. Additional testing is needed.

It is very important that you take the next step. We will call you or you may call us at <NUMBER> to schedule a follow-up test called a colonoscopy. During a colonoscopy, the doctor gives you some medicine to help you relax so it’s like you are asleep. Then the doctor uses a long flexible tube to check your whole colon. The test usually takes 15 to 30 minutes, depending on whether a growth, such as a polyp, needs to be removed. Afterward, you wait for the relaxing medicine to wear off and someone will have to drive you home.

A copy of your results is with your doctor at <SITE>.

If you have questions about your results or how to schedule a colonoscopy please call <NUMBER>.

Sincerely,

<PROVIDER SIGNATURE>
<PROVIDER PREFIX, PROVIDER FIRST, LAST NAME>
Appendix K. Sample CRC Awareness Items for Community-Wide Events

1. Sample* CRC Awareness T-shirt:

*Sample shirt. To be approved by KCP, CAG, and focus groups prior to printing. Will alter text on the back to coincide with events when worn at event (e.g. “Maysville Fall Festival 2019”)

2. CRC Awareness Wristbands:

3. CRC Awareness Grocery Totes:
### Appendix L. Gantt Chart

#### Study Timeline for Meeting Goals & Objectives

<table>
<thead>
<tr>
<th>Task</th>
<th>Y1</th>
<th>Y1</th>
<th>Y1</th>
<th>Y2</th>
<th>Y2</th>
<th>Y2</th>
<th>Y3</th>
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<td>Q2</td>
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<td>Q3</td>
<td>Q1</td>
<td>Q2</td>
<td>Q3</td>
<td>Q4</td>
</tr>
<tr>
<td>Conduct FIT Pack Liaison Training</td>
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<tr>
<td>Conduct clinician baseline surveys at participating clinic sites</td>
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<td>X</td>
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<tr>
<td>Randomize clinics to Early Intervention vs. Delayed Intervention</td>
<td>X</td>
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<tr>
<td>Conduct Clinic Staff Training for Early Intervention group</td>
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<tr>
<td>Early Intervention Period</td>
<td></td>
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<td>X</td>
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<tr>
<td>Evaluate outcomes data from Early Intervention vs. Usual Care Period</td>
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<tr>
<td>Conduct Patient Satisfaction Surveys for Early Intervention Patients</td>
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<tr>
<td>Delayed Intervention Period</td>
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<td>X</td>
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<tr>
<td>Conduct Patient Satisfaction Surveys for Delayed Intervention Patients</td>
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<td>X</td>
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<tr>
<td>Sustainability Period for Early Intervention Group</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Sustainability Period for Delayed Intervention Group</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Conduct clinician post-intervention surveys at participating clinic sites</td>
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<td>Conduct final data analyses</td>
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<tr>
<td>Local, state, and national conference presentations</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Manuscript Write-Up</td>
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<td>X</td>
</tr>
</tbody>
</table>
Appendix M. Clinician Survey

Please answer the following questions about the US Preventative Services Task Force (USPSTF) current recommendations for colorectal cancer screening (CRCS) based on your current knowledge and to the best of your ability, without looking it up.

1. The USPSTF recommends CRCS for which of the following age groups, assuming no other comorbidities or family history?
   - Age 40 and over
   - Age 50 and over
   - Age 50 - 75
   - Age 45 - 70

2. For patients in the recommended age range with no bowel-related comorbidities, family history, or history of abnormal colonoscopy, how often is colonoscopy recommended for screening?
   - Every 1 year
   - Every 5 years
   - Every 7 years
   - Every 10 years

3. For patients in the recommended age range with no bowel-related comorbidities, family history, or history of abnormal colonoscopy, how often is a fecal immunochemical test (FIT) or fecal occult blood test (FOBT) recommended for screening?
   - Every 1 year
   - Every 5 years
   - Every 7 years
   - Every 10 years

4. Please rank the following colorectal screening modalities from very effective to not effective at detecting colorectal cancer (CRC).
   a. Guaiac-based FOBT
      - Very effective
      - Somewhat effective
      - Not effective
      - Don’t know
   b. Immunochemical FOBT
      - Very effective
      - Somewhat effective
      - Not effective
      - Don’t know
   c. Flexible Sigmoidoscopy
      - Very effective
      - Somewhat effective
      - Not effective
      - Don’t know
   d. Colonoscopy
      - Very effective
      - Somewhat effective
      - Not effective
      - Don’t know

Please rate your agreement with the following statements about colonoscopies.

5. Colonoscopy is the best CRCS test.
   - Strongly agree
   - Somewhat agree
   - Somewhat disagree
   - Strongly disagree

6. Colonoscopy is readily available for my patients.
   - Strongly agree
   - Somewhat agree
   - Somewhat disagree
   - Strongly disagree
7. Colonoscopy is available, but many of my patients face financial barriers to colonoscopy screening.
   - Strongly agree
   - Somewhat agree
   - Somewhat disagree
   - Strongly disagree

8. I worry that I might be sued if I don’t recommend colonoscopy to my patients.
   - Strongly agree
   - Somewhat agree
   - Somewhat disagree
   - Strongly disagree

For questions 9-13, please rate how often you encounter the following barriers in patient knowledge and attitudes about CRCS.

9. My patients do not perceive colorectal cancer as a serious health threat.
   - Always
   - Usually
   - Sometimes
   - Usually not
   - Never

10. My patients are unaware of colorectal cancer screening.
    - Always
    - Usually
    - Sometimes
    - Usually not
    - Never

11. My patients do not want to discuss colorectal screening.
    - Always
    - Usually
    - Sometimes
    - Usually not
    - Never

12. My patients have difficulty understanding the information I present about colorectal cancer screening.
    - Always
    - Usually
    - Sometimes
    - Usually not
    - Never

13. I will not order a CRCS test if I think the patient is unlikely to complete the test.
    - Always
    - Usually
    - Sometimes
    - Usually not
    - Never

Please answer questions 11-13 about your institution’s CRCS strategies.

14. Our primary care office regularly receives quality reports on our CRCS rates.
    - Yes
    - No
    - Don’t know

15. Our primary care office currently uses the following strategies to educate patients about CRCS (select all that apply):
    - Posters/brochures in waiting room
    - Brochures given to patients
    - Clinicians discuss screening with patients
    - Staff discuss screening with patients
    - Electronic media in waiting room
    - Letters mailed to patients
    - Other (please describe):

16. Our office has access to the following to remind me who is due for CRCS (select all that apply):
    - Health maintenance flow sheet
    - Alert or prompt in electronic health record
    - Staff reviews patient record and notifies me


Practice has a mechanism to offer screening w/o my direct involvement (e.g., MAs give out FOBTs, standing orders)
Medical assistant or other staff hands out an FOBT kit
Standing orders to refer for endoscopy
Other (please describe):
__________________________________________________________________________________
___________________________________
None of the above

For the following questions, please rate how you perceive the helpfulness of the following potential interventions to improve CRCS from very helpful to very unhelpful (regardless of whether or not you think your clinic is able to implement these interventions).

17. Implementation of EHR alerts to notify staff about which patients need screening
   ○ Very helpful   ○ Somewhat helpful   ○ Somewhat unhelpful   ○ Very unhelpful

18. Implementation of EHR alerts to notify clinicians about which patients need screening
   ○ Very helpful   ○ Somewhat helpful   ○ Somewhat unhelpful   ○ Very unhelpful

19. Improved access to diagnostic colonoscopy for patients with a positive FOBT or FIT
   ○ Very helpful   ○ Somewhat helpful   ○ Somewhat unhelpful   ○ Very unhelpful

20. Generation of a list of patients coming in each day who need CRCS
   ○ Very helpful   ○ Somewhat helpful   ○ Somewhat unhelpful   ○ Very unhelpful

21. Mailed FOBT or FIT test kits to patients who are due for screening
   ○ Very helpful   ○ Somewhat helpful   ○ Somewhat unhelpful   ○ Very unhelpful

For the next questions, please rate how likely you believe your clinic would be capable of implementing the following interventions (regardless of whether or not you think they would be helpful to increase CRCS).

22. Implementation of EHR alerts to notify staff about which patients need screening
   ○ Very likely   ○ Somewhat likely   ○ Somewhat unlikely   ○ Very unlikely

23. Implementation of EHR alerts to notify clinicians about which patients need screening
   ○ Very likely   ○ Somewhat likely   ○ Somewhat unlikely   ○ Very unlikely

24. Improved access to diagnostic colonoscopy for patients with a positive FOBT or FIT
   ○ Very likely   ○ Somewhat likely   ○ Somewhat unlikely   ○ Very unlikely

25. Generation of a list of patients coming in each day who need CRCS
   ○ Very likely   ○ Somewhat likely   ○ Somewhat unlikely   ○ Very unlikely

26. Mailed FOBT or FIT test kits to patients who are due for screening
   ○ Very likely   ○ Somewhat likely   ○ Somewhat unlikely   ○ Very unlikely

Please answer the following questions specific to you and your job:
27. What is your profession?
   ○ Physician
   ○ Nurse Practitioner
   ○ Physician Assistant
   ○ Registered Nurse
   ○ Pharmacist
   ○ Technician
   ○ Clerk
   ○ Other (please specify): _________________________________

23. At which clinic are you currently working?
   ○ Bracken County Health Department
   ○ Bracken County PrimaryPlus Clinic
   ○ Buffalo Trace District Health Department
   ○ Fleming County Health Department
   ○ Fleming County PrimaryPlus Clinic
   ○ Lewis County Health Department
   ○ Lewis County PrimaryPlus Clinic
   ○ Mason County PrimaryPlus Clinic


Appendix N. Patient Satisfaction Survey

1. I took the at-home blood stool test recently sent to me by my doctor.
   ○Yes
   ○No

For patients who answered “yes” to Question 1, proceed to questions 2-8. For patients who answered “no” to Question 1, skip to Question 9.

2. I thought the test was convenient.
   ○Strongly agree   ○Somewhat agree   ○Somewhat disagree   ○Strongly disagree

3. I thought the instructions were easy to understand.
   ○Strongly agree   ○Somewhat agree   ○Somewhat disagree   ○Strongly disagree

4. I thought the test was easy to do.
   ○Strongly agree   ○Somewhat agree   ○Somewhat disagree   ○Strongly disagree

5. I would be willing to do this test again next year if it were mailed to me.
   ○Strongly agree   ○Somewhat agree   ○Somewhat disagree   ○Strongly disagree

6. I would be willing to schedule a doctor's appointment next year to get another test just like this one with my regular check-up.
   ○Strongly agree   ○Somewhat agree   ○Somewhat disagree   ○Strongly disagree

7. How likely are you to screen for colorectal cancer again in a year?
   ○Very likely   ○Somewhat likely   ○Somewhat unlikely   ○Very unlikely

8. How can we make it easier for you to screen for CRC? (free response)

Questions 9 and 10 are for patients who answered “no” to Question 1.

9. I did not take the test because:
   ○I am too busy
   ○The test takes too much time
   ○I am afraid of the results
   ○I do not believe I need to be screened for colorectal cancer at this time
   ○I believe I am up-to-date with colorectal cancer screening
   ○I did not want to perform the test or I thought it was “gross”
   ○I think the test is embarrassing
   ○I was confused by the instructions
   ○I am not physically able to perform the test on my own
   ○Other (please specify): ______________________________________________________

9. How likely are you to screen for CRC in the next 6 months?
   ○Very likely   ○Somewhat likely   ○Somewhat unlikely   ○Very unlikely
Appendix O. Budget and Justification

Project Title: Increasing Colorectal Cancer Screening with a Mailed FIT Program

Time period: 6/1/2018 – 5/31/2021

A. Salaries and Wages

<table>
<thead>
<tr>
<th>Staff Member</th>
<th>Effort</th>
<th>Salary</th>
<th>Fringe</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Year 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Director</td>
<td>25.00%</td>
<td>$100,000</td>
<td>$7,999</td>
<td>$32,999</td>
</tr>
<tr>
<td>Project Coordinator</td>
<td>100.00%</td>
<td>$58,000</td>
<td>$23,070</td>
<td>$81,070</td>
</tr>
<tr>
<td>FIT Pack Liaison</td>
<td>75.00%</td>
<td>$50,000</td>
<td>$16,027</td>
<td>$53,527</td>
</tr>
<tr>
<td>MPH Graduate Student</td>
<td>12.50%</td>
<td>$27,040</td>
<td>$924</td>
<td>$4,304</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Year 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Director</td>
<td>25.00%</td>
<td>$107,097</td>
<td>$8,456</td>
<td>$35,230</td>
</tr>
<tr>
<td>Project Coordinator</td>
<td>100.00%</td>
<td>$60,913</td>
<td>$24,011</td>
<td>$84,925</td>
</tr>
<tr>
<td>FIT Pack Liaison</td>
<td>75.00%</td>
<td>$53,841</td>
<td>$16,881</td>
<td>$57,262</td>
</tr>
<tr>
<td>MPH Graduate Student</td>
<td>25.00%</td>
<td>$27,040</td>
<td>$1,848</td>
<td>$8,608</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Year 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Director</td>
<td>25.00%</td>
<td>$110,310</td>
<td>$8,710</td>
<td>$36,287</td>
</tr>
<tr>
<td>Project Coordinator</td>
<td>90.00%</td>
<td>$62,741</td>
<td>$22,258</td>
<td>$78,725</td>
</tr>
<tr>
<td>FIT Pack Liaison</td>
<td>45.00%</td>
<td>$64,779</td>
<td>$11,324</td>
<td>$40,475</td>
</tr>
<tr>
<td>MPH Graduate Student</td>
<td>25.00%</td>
<td>$27,040</td>
<td>$1,848</td>
<td>$8,608</td>
</tr>
</tbody>
</table>

The program will provide salaries for its Project Director, Project Coordinator, and a community health worker known as a FIT Pack Liaison as a member of the project leadership team, and part-time funding for an MPH graduate student who will participate in the data collection, participant communication, clerical duties, and abstract and manuscript development. Yearly salaries for the Project Director and Program Manager were determined by assessing the level of education and experience required of each member of the program’s staff and pulling salary data from the CDC Budget Preparation Guidelines. [29] [28] The FIT Pack Liaison’s salary was established by researching average
community health worker salaries through the U.S. Department of Labor’s Bureau of Labor Statistics. We anticipate FIT Pack Liaisons will work approximately 30 hours per week for the first year. This will include 3.5 to 4 days per week of training, conducting clinic site visits for healthcare professional training, and biweekly visits to each clinic site during the intervention period. Because the final year of the grant period is a sustainability period, we anticipate the FIT Pack Liaisons will only work one day a week to provide oversight to clinic staff. Finally, the MPH graduate student salary was determined by assuming he or she will work 10 hours a week at $13.00 per hour. Because implementation and outcomes data collection will not begin until after month six of the first year, the salary for the MPH student in the first year is half of what it will be in years two and three of the grant period.

**Fringe Benefits:** Fringe benefits were calculated based on staff salaries and the University of Kentucky’s fringe benefits schedule, which can be found at the following link:

[http://www.research.uky.edu/ospa/info.html](http://www.research.uky.edu/ospa/info.html)

**Travel Expenses**

<table>
<thead>
<tr>
<th>Travel - total</th>
<th>Year 1 Amount ($)</th>
<th>Year 2 Amount ($)</th>
<th>Year 3 Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mileage</td>
<td>4000</td>
<td>7000</td>
<td>6000</td>
</tr>
<tr>
<td>Conferences</td>
<td>4000</td>
<td>4000</td>
<td>3000</td>
</tr>
<tr>
<td></td>
<td>3000</td>
<td>3000</td>
<td></td>
</tr>
</tbody>
</table>

Travel costs are minimal during the first year of the program, as there will be limited data for presentation at state and national conferences. The program budgets for a maximum of 200 miles of driving per month during the first two years of the program. FIT Pack liaisons will conduct biweekly site visits to intervention clinics and monthly site visits to clinics in
the sustainability phase, and site visits in nearby counties will be conducted on the same
days to reduce gas mileage and travel time. For example, a monthly visit to the Lewis
County Health Department will be scheduled for the same day as a biweekly site visit to the
PrimaryPlus clinic in Lewis County. Because the final year of the program will require only
monthly site visits, we have budgeted for the FIT Pack Liaison to need gas for only 100
miles per month.

Conference travel is budgeted into years two and three. The Program Director and
Project Manager will be expected to attend one national meeting of their own preference
based on its relevance to this program and one state KPHA meeting. [28]

### Focus Groups

<table>
<thead>
<tr>
<th></th>
<th>Year 1 Amount ($)</th>
<th>Year 2 Amount ($)</th>
<th>Year 3 Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus groups</td>
<td>1150</td>
<td>1150</td>
<td>1150</td>
</tr>
<tr>
<td>Food</td>
<td>350</td>
<td>350</td>
<td>350</td>
</tr>
<tr>
<td>Incentives</td>
<td>800</td>
<td>800</td>
<td>800</td>
</tr>
</tbody>
</table>

Focus group meetings will occur quarterly within public areas, such as conference rooms
provided by the city hosting each focus group or multi-purpose rooms provided by county
health departments. The program also requests $350 for meals at community member
focus groups; we are planning to conduct three focus groups with 10 community members
each quarter. The program budgets $8.00 per meal. In addition, the program budgets $800,
or approximately $20.00 per attendee, to spend on incentives for community members to
attend these focus group meetings in the form of Visa gift cards.
Trainings

<table>
<thead>
<tr>
<th></th>
<th>Year 1 Amount ($)</th>
<th>Year 2 Amount ($)</th>
<th>Year 3 Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trainings</td>
<td>10400</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Time for participants (fee for service)</td>
<td>9600</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Food</td>
<td>800</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Clinic staff members who participate in each training session during the first year will be compensated for their time. Each of the eight sites participating in this program will send three staff members (a nurse manager and two providers) to two four-hour training sessions. Assuming average pay of $50 per hour, this program has budgeted $9,600 to compensate them for their time at these sessions. The program has also budgeted for the cost of food at approximately $10.00 per person for training sessions.

Supplies

<table>
<thead>
<tr>
<th></th>
<th>Year 1 Amount ($)</th>
<th>Year 2 Amount ($)</th>
<th>Year 3 Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIT Kits</td>
<td>10,000</td>
<td>10,000</td>
<td>0</td>
</tr>
<tr>
<td>Mailing Supplies &amp; Postage</td>
<td>14000</td>
<td>14000</td>
<td>0</td>
</tr>
<tr>
<td>Educational Flyers</td>
<td>500</td>
<td>500</td>
<td>0</td>
</tr>
<tr>
<td>Promotion Prizes</td>
<td>500</td>
<td>500</td>
<td>500</td>
</tr>
</tbody>
</table>

FIT kits will be billed to patient insurance plans, if patients have insurance plans that cover FIT kits. This program has budgeted $10,000 per year in the first two years of the grant period to cover the cost of Polymedco OC LIGHT-S® (Polymedco, Inc., Cortlandt Manor, New York) tests at approximately $10 per test. Although most commercial insurance policies, Medicare, and Medicaid cover the cost of FIT tests, unreturned tests cannot be billed to insurance. We also anticipate that anywhere from 15-30% of the patients served
will not have insurance coverage based on the current uninsured rate of 10.8% across the Buffalo Trace ADD[30], so the program will cover the cost of these tests.

We request $14,000 per year to mail FIT kits to eligible patients who agree to screening, based on a budget of $14.00 total for mailing each FIT kit with a prepaid return label. This will allow the program to send up to 1,000 FIT kits over each intervention period. During sustainability periods, the program will not pay for FIT kits, and participating sites will be responsible for maintaining screening practices with program staff oversight.

### Incentives

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinic Staff Survey Incentives</strong></td>
<td>1000</td>
<td>0</td>
<td>1000</td>
</tr>
<tr>
<td><strong>Patient FIT Return Incentives</strong></td>
<td>5000</td>
<td>5000</td>
<td>0</td>
</tr>
</tbody>
</table>

Incentives for patients are estimated to cost $7000 total each year for the first two years. Each participant who returns a completed FIT kit within 14 days of mail-out will receive a T-shirt (pictured in Appendix K) at a cost of $5.00 per shirt. Assuming 1000 FIT Kits are returned over each intervention period, the program budgets $5000 per year during the first two years. During the sustainability period, healthcare systems will be responsible for incentivizing CRCS, and the program will not pay for screening incentives. The program will continue to pay for patient satisfaction survey incentives during this period to finalize outcomes evaluations. The program has budgeted $2000 per year to send each patient who returns a survey (1000 estimated) a $2.00 grocery bag (pictured in Appendix K).
Clinic staff will be incentivized to participate in CRCS knowledge, awareness, and intervention readiness surveys with the opportunity to win one of ten $100 Visa gift cards. Because these surveys will only be administered during years one and three of the grant period, we have not budgeted for clinician incentives during year two.

**Clinic Participation Stipend**

<table>
<thead>
<tr>
<th></th>
<th>Year 1 Amount ($)</th>
<th>Year 2 Amount ($)</th>
<th>Year 3 Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic Participation Stipend</td>
<td>40,000</td>
<td>$40,000</td>
<td>$40,000</td>
</tr>
</tbody>
</table>

The program will provide participating clinics with $8,000 each for allowing program staff to conduct data retrieval at participating sites during the sustainability period once the program is no longer providing FIT Packs and patient outreach with clinic staff. Although the DI clinics will not be in the sustainability period yet during year two, the program has budgeted to allot money during this time to maintain fairness across participating clinics. This money will be for clinic administrators to use as they see fit.

**Consultant Costs**

<table>
<thead>
<tr>
<th></th>
<th>Year 1 Amount ($)</th>
<th>Year 2 Amount ($)</th>
<th>Year 3 Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant &amp; Contracting Costs</td>
<td>$5,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The program will contract out with a computer programmer, who will come onsite once prior to the implementation period and quarterly thereafter until the conclusion of year two. Given the average salary of approximately $42 per hour, the program plans to pay for approximately fourteen total days of the computer programmer’s time at the start of the
grant period. This will allot time for establishing baseline and quarterly lists of established patients within each clinic system and creating an algorithm by which clinic staff may generate these lists on their own during the sustainability period.