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IMPROVING COLORECTAL CANCER SCREENING RATES IN PERRY COUNTY

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IMPROVING COLORECTAL CANCER SCREENING RATES IN PERRY COUNTY

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

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Project Abstract

Appalachian Kentucky has one of the highest incidence and mortality rates from colorectal cancer (CRC) in the country. CRC is curable if identified early through screening. However, Perry County has suboptimal screening levels. A multimodal program of patient reminders and mailed screenings will be used to increase CRC screening rates in Perry County. The primary outcome will be evaluated using a T-test for this prospective cohort study. Short term outcomes include increased CRC screening rates in delinquent patients. Long term outcomes include increased CRC detection rates and decreased CRC mortality in Perry County.

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Section I – Target Population and Need

Ia: Description of Need

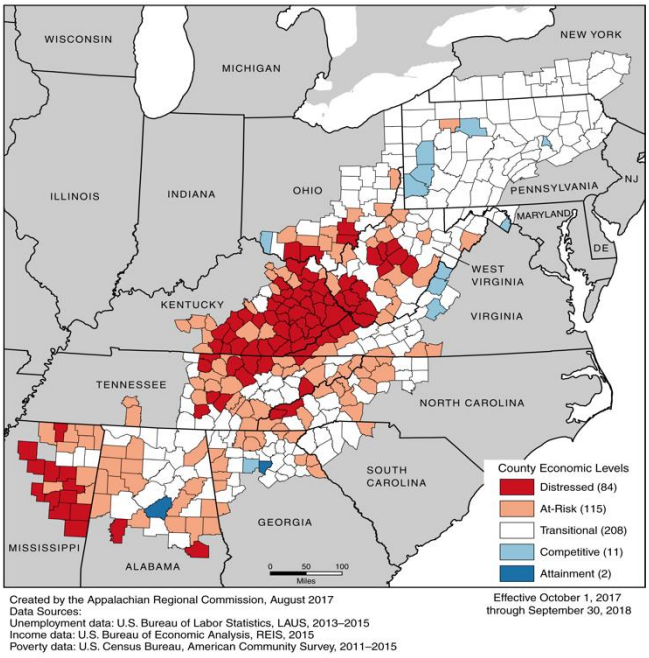


Figure 1

Appalachia is a low-resourced area with a dense, vulnerable population. It spans a 205,000 square mile region from southern New York to northern Mississippi, and consists of 13 states, including Kentucky. The Appalachian region has been identified as a medically underserved region due to the financial, geographic, and health system challenges in the region [1]. There are significant health disparities for people living in Appalachia including, but not limited to financial constraints, environmental delays, and lack of knowledge about the implications of disease and treatment options [2]. Kentucky's Appalachian counties are some of the most economically distressed counties in the Appalachian region and the U.S., and this context is linked to some of the worst health outcomes in the nation [3] (Fig. 1). This is even more salient with the health disparities and outcomes surrounding cancer.

Kentucky has the highest incidence of cancer in the country and also ranks highest in the incidence of colorectal cancer (CRC) (49.2 per 100,000, compared to nationwide at 38.7 per 100,000) [4]. The mortality associated with CRC is higher in Kentucky (16.6 per 100,000) compared to the national average (14.2 per 100,000) [4]. In

Kentucky's Appalachian counties, there is also a higher mortality rate in patients diagnosed with colon cancer compared to non-Appalachian counties. Colon cancer mortality in Kentucky's Appalachian counties is 19.8 per 100,000, compared to state average of 16.6 per 100,000 [3, 5] (Table 1).

Table 1 - Incidence, Mortality, and Screening Rates with Colorectal Cancer (2012-2016)

Location	Screening	Incidence*	Mortality*
Perry County	N/A	57.7	17.4
Appalachian Kentucky	N/A	55.0	19.8
Kentucky	69.7%	49.2	16.6
National	67.3%	38.7	14.2

***Rates per 100,000**
Data adapted from United States Center for Disease Control and the Kentucky Cancer Registry

As noted in Table 1, Appalachian Kentucky counties have a significantly higher mortality rate from CRC compared to the state and national averages. This increase in mortality is likely attributable to the significantly higher incidence rates of CRC. Kentucky also has a nearly 12 per 100,000 incidence rate increase compared to the national average, which is shown in Table 1. This is even higher in the Appalachian region of Kentucky at 55 per 100,000 population.

Incidence and mortality of CRC is directly associated with rates of CRC screening. CRC is curable if identified early in the disease process, leading to improved survival. While the state of Kentucky appears to have higher than national average CRC screening rates, granular data separating by Appalachian region is not available. However, it is well known that rural regions have significantly lower CRC screening rates compared to urban areas [6] (Fig. 2). Research conducted by Ojinakka et al. have

shown that rural and non-metropolitan dwellers had 30% decreased odds of being screened for CRC compared to metropolitan residents [7].

Additionally, there is an elevated incidence and mortality of colorectal cancer in Appalachian Kentucky. By identifying CRC earlier in the disease process through screening, curative treatment can be provided and mortality can be decreased. Therefore, it is imperative to have targeted interventions aimed at increasing screening rates in this community.

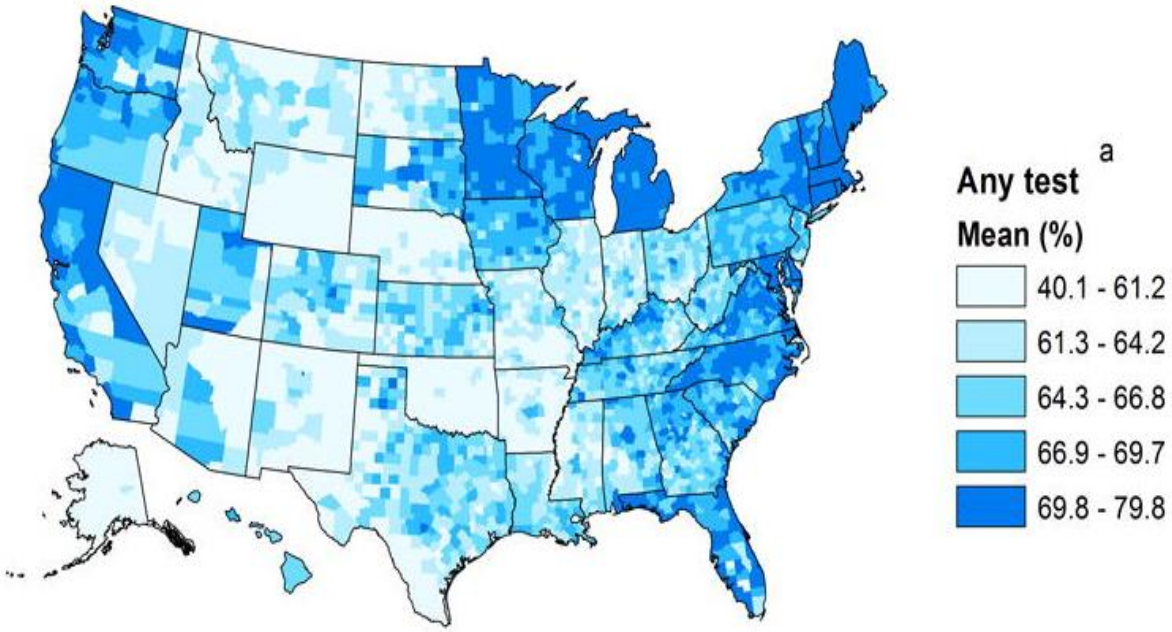


Figure 2 – Nationwide CRC Screening Rates - Adapted from Berkowitz et al., 2018

Ib: Description of Target Community

The intervention will be targeted at patients eligible for CRC screening in Perry County, Kentucky, which is a county in the Appalachian region with 27,329 residents. Demographically, the population of Perry county is 95.6% white. The median household

income is $31,280 and 26.2% of the population lives below the poverty line. There are 889 patients per primary care physician in the county. In 2019, Perry County ranked 119th out of the 120 counties in Kentucky in health outcomes (length of life and quality of life) and premature death. The latter is an age-adjusted measure of deaths under the age of 75. As is the case with nearly 90% of Appalachian counties in Kentucky, the most common cause of the premature death in Perry County is also due to malignant neoplasms [8]. Approximately 302 per 100,000 residents in Perry County die from malignant neoplasms per year [9]. This county was selected for the intervention due to its staggeringly low performance in overall health outcomes, along with the significant need in this community for improved CRC screening.

IC: Description of Community Resources

Primary Care Centers of Eastern Kentucky is a well-established healthcare organization, serving the eastern Kentucky region since 2003. The organization has been recognized a Patient Centered Medical Home nationally and aims to provide coordinated and comprehensive care. They provide preventative care services, including CRC screening to their patients.

Hazard Appalachian Regional Healthcare is a 358-bed acute care hospital, with associated primary care clinics. It is an accredited cancer center that provides CRC screening and treatment services. This center is a 10,000 square foot treatment center dedicated to the care of patients with malignant diseases.

University of Kentucky Northfork Valley Community Health Center is a community health center in Hazard, KY. It serves patients regardless of their income or ability pay. Additionally, the clinic has a sliding fee scale to help reduce the financial

burden for patients. Combined, the three organizations have over 60 primary care providers delivering healthcare services to the majority of the county.

Community needs were identified by consolidating data from various sources. The 2019 Perry County Community Assessment conducted by the University of Kentucky, which demonstrated that one of the primary goals of the community was to decrease chronic diseases, including cancer [10]. Furthermore, the community's aggregate health status results were reviewed in the County Health Ranking Database. This is a database funded by the Robert Wood Johnson Foundation that provides a detailed overview of the health of a community. Since this program involves a single implementation, ongoing community needs assessment is not required.

Another resource in the community is the high level of health insurance coverage. In Perry County, 91.2% of the population has health insurance coverage, with 31.5% on employee plans, 35.1% on Medicaid, 14.5% on Medicare, and the remainder in non-group or Veterans Affairs plans [11].

Section II – PROGRAM APPROACH

IIa: Description of Standard Screening Practice for CRC

Per the United States Preventive Services Task Force guidelines, CRC screening is recommended for all adults between 50 and 75 years of age [12]. There are different methods of identifying if the patient has a polyp, such as screening colonoscopies, fecal immunochemical test (FIT), Cologuard fecal test, or CT colonography, as noted in Table 2. Once a patient is identified as having a polyp, they are recommended to undergo a diagnostic colonoscopy, where polyps are biopsied and

if malignant, further treatment is considered. If the polyp is able to be completely removed endoscopically, the patient requires no further surgical or medical treatment. Future polyps are identified through frequent screenings. If the polyp cannot be removed endoscopically, then the patient requires a surgical resection. The resection type is dependent on the location of the polyp in the colon and the concern for metastasis.

The gold-standard for screening for CRC is a colonoscopy. This is a procedure in which the patient is sedated and a long tube with a camera at the end is inserted into the colon to assess the colonic wall for polyps and other suspicious lesions. Lesions can be biopsied and sometimes removed during the course of this procedure. However, this procedure requires a significant amount of prior preparation, requires the patient to travel to the healthcare facility, and requires that the patient have a chaperone to drive them after the procedure. Additionally, colonoscopies are resource intensive, from a healthcare system standpoint. They require a qualified physician (typically a surgeon or a gastroenterologist) to perform the colonoscopy, access to facilities with anesthesia monitoring, recovery facilities, and resources to manage any complications that may occur. These barriers, along with others, have led to poor adherence to CRC screening, even though it is the gold-standard [13-15]. Specifically, colonoscopy is often perceived poorly by patients, especially in the Appalachian region. Attarabeen et al. found “feelings associated with [CRC] screening included embarrassment, discomforted at being ‘poked’ or ‘prodded’, powerlessness, avoidance, worry, and even disgust” [16]. In this subset of patients who are resistant to traditional screening methods, alternative approaches are needed to improve screening rates.

One such alternative test is CT Colonography, which uses x-rays to obtain a three-dimensional image of the colon and rectum to evaluate for any abnormalities. This requires the patient to travel to the healthcare facility to obtain the test. Additionally, it requires significant infrastructure and personnel resources from the healthcare facility to administer. Furthermore, there is radiation exposure associated with this test.

Cologuard and FIT are alternative, less invasive tests that can be performed by the patient in the comfort of their home. Patients receive a prepaid package, in which they will send a stool sample. These stool samples are tested for specific DNA (Cologuard) or blood (FIT) to identify the risk of CRC in these patients. If the test is positive, the healthcare organizations are informed, who then inform the patient. FIT and Cologuard are similar in many ways. They are both tests that patients can take in the comfort of their home and can be mailed to the lab. However, there are some key differences that make Cologuard more suitable for this population. If Cologuard is used as a test and is negative, patients need to repeat it every three years, compared to FIT which needs to be repeated annually. Additionally, Cologuard is more sensitive and specific than FIT, since it evaluates for abnormal DNA.

If any of the three aforementioned alternative tests are positive, the patient would need to undergo a colonoscopy to further evaluate their colon.

Table 2 – CRC Screening Modalities

Name	Definition	Benefits	Risks	Next Steps
Cologuard	At home test that looks for blood or DNA released by colorectal cancer or polyps.	• Don't have to leave home. • No preparation required. • Non-invasive test	• None	• If positive, a colonoscopy is recommended. • If negative, test should be repeated every 3 years.
Colonoscopy	A procedure done at the hospital that looks at the rectum and colon using a flexible camera scope.	• Can examine the entire colon • Suspicious polyps can be removed and examined for cancer.	• Invasive procedure • Sedation required • Small risk of bleeding, bowel tear, or infection	• If positive, your doctor will talk with you about how to move forward. • If negative, colonoscopy should be repeated every 10 years.
CT Colonography	A test that creates a 3D x-ray image of the rectum and colon with a flexible scope will be placed in the rectum	• Can examine the entire colon • Does not require sedation	• Invasive procedure • Uses x-ray radiation • Cannot remove any polyps	• If positive, must be followed by a colonoscopy. • If negative, the test should repeated every 5 years.
Fecal Immunochemical Test (FIT)	An at home test that looks for blood released from colorectal cancer or polyps.	• Collect a stool sample in the comfort of your own home • Non-invasive	• Does not detect cancer or polyps that are not bleeding	• If positive, a colonoscopy is recommended. • If negative, test should be repeated every year.

Adapted from Chablani et al.

IIb: Description of Current Practices

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provides for an incentive program to ensure quality in healthcare delivery. One of the measures tracked and incentivized by MACRA is CRC screening. Therefore, every healthcare practice is required to track the patients in the practice that receive CRC screening.

In a typical primary care practice, the electronic medical record (EMR) identifies patients who are eligible for CRC screening. When such a patient arrives for an appointment, the EMR notifies the patient's healthcare provider that the patient is eligible for CRC screening. Then, it is up to the healthcare provider to discuss CRC screening during the patient's appointment. If the patient agrees to a screening modality, the patient is either sent a fecal testing kit or is scheduled for a procedure. Once the results of the screening test are available, the provider follows up with the patient regarding the next steps.

However, this process has several challenges. Providers may fail to discuss CRC screening or may have inadequate CRC screening discussions with the patients for

several reasons. Studies have shown that primary care providers don't adequately follow CRC screening guidelines, and don't necessarily share all options for screening with their patients [17-20]. Additionally, when providers do discuss CRC screening, they often only discuss colonoscopies as an option [17]. As mentioned above, Appalachian patient perceptions regarding colonoscopies can act as barriers. Appalachian Kentuckians report "fear, embarrassment, financial issues, lack of perceived need, qualities of the test, lack of provider recommendation, and health care delivery barriers" as challenges to CRC screening [21]. To address these challenges with CRC screening, a multimodal approach needs to be utilized to increase the rates of CRC screening in this community.

IIc: Description of Evidence-Based Intervention

The proposed intervention consists of a multimodal approach to increase CRC screening rates in patients resistant to traditional CRC screening. This intervention will be implemented from three settings: Primary Care Centers of Eastern Kentucky, University of Kentucky North Fork Valley Clinic, and the Hazard Appalachian Regional Healthcare (ARH) Medical Center. Together, these three settings provide a large portion of the healthcare for this community.

The intervention will be the similar at all three locations. Patients between the age of 50 and 75 years who receive health care services at the above facilities, and have not had CRC screening will be identified by querying the electronic medical records at each facility. Since all three locations have an electronic medical record, patients who are resistant to screening will be tracked. As mentioned above, as a part of the MACRA measures, all healthcare practices are required to track CRC screening.

Each of these patients will be contacted multiple times by a nurse or healthcare provider at the healthcare facility. The first time they are contacted will be through a phone call, during which patients will be briefed regarding the importance of CRC screening and informed that they will be receiving a test in the mail. The steps of how to use the in-home screening will also be described and any questions patients may have will be answered. Following the phone call, each patient will be mailed a Cologuard test kit, with a pre-paid box to return the sample. The kit will include literacy level appropriate directions, created with the assistance of the community advisory board (see below). Upon receiving the Cologuard kit, patients will be asked to place a small stool sample in the kit, seal it, and mail it back. Approximately a month after mailing Cologuard, patients who have not completed their Cologuard screening will be contacted by phone and reminded to complete the screening. These patients will be identified in the Cologuard database by graduate assistants on a weekly basis. The list of patients who have not completed their screening within a month will be provided to the nurses on staff.

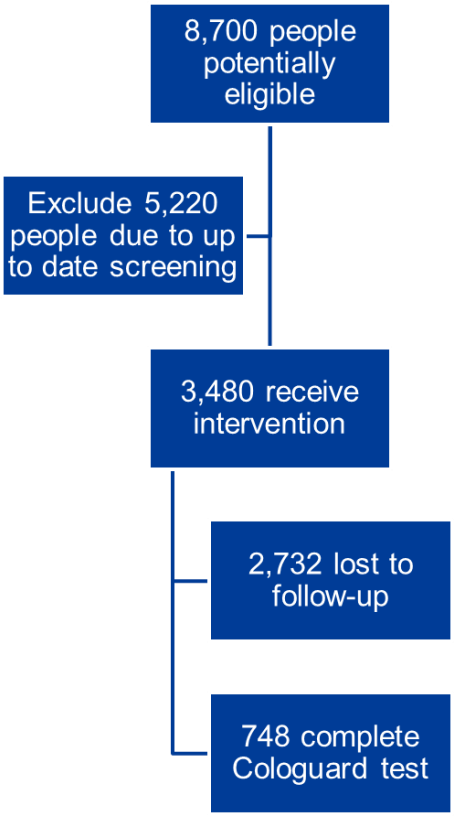
Once the results of the test are received by the healthcare facility, the aforementioned nurses will contact all patients by phone to inform them of the results. If there is concern for malignancy, the patient will be assisted in scheduling a colonoscopy with a local health care provider for further evaluation. If negative, the patient will still be informed of the results by phone. They will also be informed that they need to repeat the test in 3 years. Additionally, each patient will receive a letter by postal mail informing them of the results and providing resources for the next steps.

This multimodal intervention, consisting of initial informative contact, screening tool mailing, and following up reminders, was selected because it has been proven to

increase CRC screening rates in resistant populations repeatedly. Several randomized control trials and other studies have shown success at increasing rates of CRC screening with multiple contact points with fecal testing [22-24]. A systematic review and meta-analysis by Dougherty et al. found that fecal blood test outreach (RR: 2.26), patient navigation (RR: 2.01), and patient reminders (RR: 1.20) increased CRC screening completion rates in US trials [25]. In the majority of these studies, patients were mailed a FIT test, with directions on how to use the test, and a pre-paid return envelope to return the test. Patients were also contacted before the test was sent out to inform them of the test. Following the mailing, they were contacted again to provide reminders. These multicomponent interventions increased the rates of CRC screening by a mean of 13% (95% CI, 7-19%) [25].

IID: Implementation

There are approximately 8,700 people between the ages of 50 and 75 years living in Perry County, according to the 2017 United States Census Bureau estimates. Screening rates in the Kentucky are hovering around 60%. With the baseline assumption that 60% of eligible patients are up to date on their CRC screening, the remaining 3,480 patients are eligible for the multimodal intervention. Patients who are overdue for their screening are defined as patients who are more than 1 year past their



due date for CRC screening. We anticipate approximately 20% participation with the Cologuard outreach, assuming that the participation rates will be similar to the literature [23]. An anticipated anticipate that a total of 1392 people in Perry County will return the test kit (Figure 3). At each intervention site, the EMR will be queried for all patients due for CRC screening. This query will be performed by the informational technology department at each location, which will result in a list of patients along with their last known contact information.

Utilizing the resources provided by this grant, one clinical nurse at each location will be trained to participate in the intervention and funded for 10% time. The clinical nurse will contact each patient on the aforementioned list and discuss CRC screening with the patient. The nurse will also inform the patient that they will be receiving a test kit in the mail and instructions on how to complete it. If the patient is not reachable on the first attempt, two further attempts will be made at different times of the day. The list of screening resistant patients is typically accurate since the healthcare practice's monetary compensation depends on it. However, if when contacted, patients state that they have already received their screening, this will be noted and they will be removed from the eligible participants list. Once contact is made, the nurse will inform Cologuard that the patient has been informed about the test. Cologuard will then send the test to the patient. If the patient has not completed the screening test within a month of receiving the Cologuard test, the clinical nurse will attempt to contact the patient again to discuss the test. By utilizing a healthcare provider from each healthcare organization to be the point of contact, the patients are more likely to have a positive response to the interaction. Successful CRC screening will be defined as return of Cologuard test kit

within 3 months of receiving it. Patients who return it after the 3 months will still be provided the results of the test and assistance with next steps, but will not be considered towards the success of this intervention.

All locations already perform CRC screening, so the addition of this method is unlikely to add a significant burden to the organizations. This multi-modal approach is likely to fit well into their current clinical protocols. Additionally, this intervention is unlikely to add excess financial burden to the healthcare organization, the increased rates of screening leading to a decrease in healthcare burden from late stage colon cancer care and the increased down-stream revenue generated by screening colonoscopies will lead to sustainability to pay for staff time. Furthermore, since a significant portion of the delinquent patients will be reached during this grant period, the healthcare organizations will not need to expend the same level of resources to continue this intervention. Their efforts will be primarily focused on the influx of newly delinquent patients, which is likely to be a small cohort. Therefore, this is likely to be sustained by the organizations after the grant period. The aforementioned methods of contacting and recruiting patients will be used because they have been shown to be effective in randomized controlled trials and other studies, with the FIT test. Since this intervention is done once every three years, participant retention is not needed.

IIe: Adaptations

Currently, the studies that evaluate the impact of multi-modal testing utilize FIT testing as the test of choice for CRC. As previously mentioned, FIT needs to be repeated every year, compared to Cologuard, which is repeated every three years. Additionally, Cologuard is significantly more sensitive than FIT, which is why our

proposal plans to use Cologuard as the CRC screening test of choice. This proposed adaptation is a minor adaptation. The process for using Cologuard or FIT is the same for participants, making a decrease in fidelity unlikely. The current literature does not have significant evidence on the usage of Cologuard in this manner, due to the relative recency of the invention of Cologuard, compared to the FIT. Additionally, there is no cost difference for the two programs to the healthcare facility or the patients because they are both completely covered by health insurances.

The second adaptation is the tailoring of Cologuard instructions to the literacy level of the community to increase fidelity of using Cologuard, since there is a decreased literacy level of this population. This is a minor adaptation and is unlikely to significantly decrease the overall fidelity.

IIf: Potential Challenges

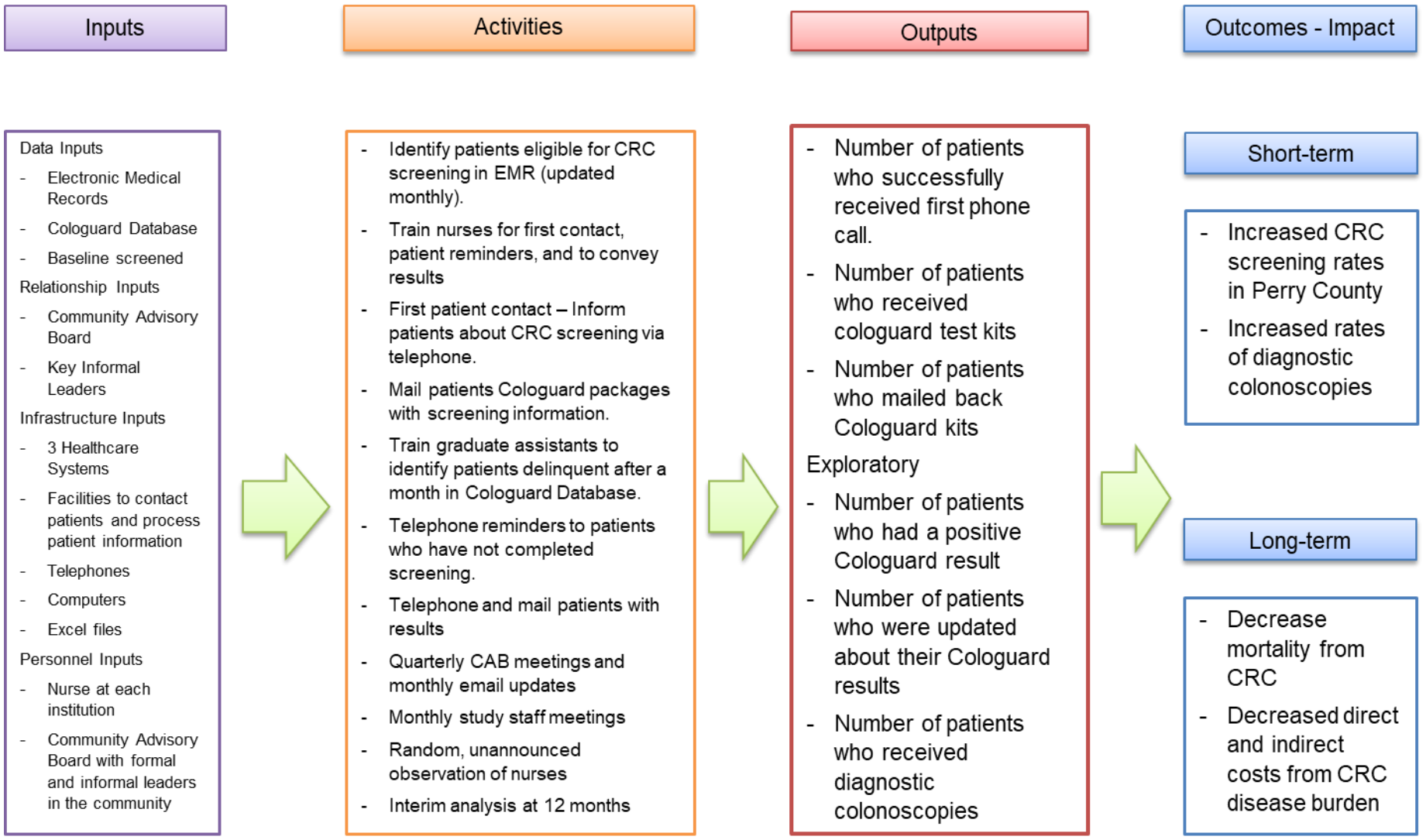
The first potential challenge is in ensuring buy-in from the three partnering healthcare organizations' leadership. One approach to overcome this obstacle is to frame the program in a way that it highlights the immediate and down-stream revenue potential for the organizations. The healthcare organizations are assisted in meeting their metrics by increasing the proportion of patients who are compliant with their screening. Additionally, each patient that has a positive Cologuard test will have a follow-up colonoscopy needed. This billable procedure is an excellent source of revenue. Furthermore, each patient with an identified diagnosis of CRC requires a surgical resection, and may also need chemotherapy. These additional hospital visits will also increase the hospital revenue, while improving health outcomes of community members.

The second potential challenge is the push back from the front-line staff in implementing this intervention with fidelity. This is a hurdle that is anticipated and will be tackled in a two-pronged approach. First, by getting buy-in from the organizational leadership, there will likely be a trickle-down effect and organizational alignment with the goals of the intervention. This may improve the fidelity of the program. Additionally, we plan on identify key informal leaders amongst front line staff and inviting them to be a part of the community advisory board. This may increase engagement with front line staff and improve their sense of investment in the intervention. These two approaches together may increase the overall fidelity of this intervention. In order to ensure that the push-back from front-line staff does not compromise the programmatic fidelity, random, unannounced observation will be conducted by the principal investigator and project manager.

The third challenge is regarding the cost of screening for uninsured patients. As mentioned above, 91.2% of the community has health insurance coverage. That leaves 8.8% of the community without health insurance. It is probable that some of the patients being screened fall within this 8.8%. In order to assist these patients with obtaining health insurance, the study will employ the social workers at each institution on an as-needed basis. Additionally, the study will budget for $10,000 to pay for Cologuard kits for patients unable to obtain health insurance. Furthermore, if uninsured patients are screened positive for CRC, they will still require additional testing and treatment. We aim to utilize our consulting social worker to assist these patients in obtaining access to insurance and provide healthcare referrals. Additionally, these patients will also be provided access to resources aimed at decreasing patient burden associated with

receiving healthcare, such as taxi vouchers, meal coupons, parking validation, and subsidized hotel rooms for family.

Improving Colorectal Cancer Screening Rates In Perry County



Section III: Performance Measures and Evaluation

The primary objective of this study is to evaluate the impact of this program on the rates of CRC screening. The success of this program will be measured by the change in screening rates before and after the implementation of this multimodal intervention. A randomized control trial (RCT) by Hendren et al. showed a multimodal approach to CRC screening had a 37.7% screening rate, compared to 16.7% in the standard group [24]. However, one challenge with our patient population is that they have already been involved in the standard screening process and are past due for their screening. Therefore, targeting a 37.7% screening rate in this resistant population is unlikely to occur. An RCT by Fortuna et al. found that the multimodal approach had a 21.5% screening rate in patients who were past due [26]. Given this evidence, a target screening rate of 21.5% at the end of the study will be used as the primary performance measure metric for the success of this intervention. Additionally, a single sample t-test will be used to analysis the overall difference in CRC rates before and after the implementation of this multimodal intervention.

Fidelity of implementation is a critical component in ensuring that the intervention is implemented as intended. There are several parts to this intervention that require careful and regular monitoring to ensure the project is on track. Regular meetings with all staff and stakeholders will be conducted to ensure that any challenges and pitfalls are averted. Additionally, the program manager will meet monthly, in-person, with the clinic nurses, and graduate students regarding current progress. The program manager and/or principal investigator (PI) will also randomly shadow the nurses while they are performing the grant activities to ensure fidelity. This will occur at least every other

month, if not more frequently. Any loss of fidelity identified will be addressed by the PI and CAB. Furthermore, the program manager will perform weekly checks on the RN patient calling logs and evaluate the graduate students tracking of cologuard database. There will also be weekly meetings between the program manager and the PI for status updates.

Additionally, there will also be monthly meetings with PI, Co-investigator, and project manager to provide status updates and trouble shooting. Every month, there will be a repeat query of the electronic medical record to identify any new patients who may meet criteria and any prior patients who may no longer meet criteria. Every month, the PI will provide email communication to the community advisory board members regarding the status of the project and any challenges. The community advisory board will meet on a quarterly basis, or more frequent if deemed necessary by the PI, to discuss the study progress and address any challenges.

At 12 months from the start of implementation, an interim analysis performed to identify the number of patients with the following attributes: received the intervention, obtained CRC screening, had a positive Cologuard test, had a diagnostic colonoscopy, received a referral to specialist, received treatment for malignancy, and mortality. Also at this time, semi-structured interviews will be conducted with all the clinical nurses to assess their knowledge, attitudes, and beliefs regarding their intervention and their progress. These results will be shared with the community advisory board and any unexpected results will be addressed.

Frontline nursing staff involved in the project will attend a full day of training, which will include an overview of the intervention and a detailed description of their roles in the

intervention. Additionally, half of the day of training will be dedicated to role playing and situational practice scenarios. Following the training, the nurses will be observed contacting the patient on a random basis by the project manager, as previously mentioned. Additional individual training will be provided as any fidelity concerns arise.

Section IV: Capacity and Experience of the Applicant Organization

Established in 1865, the University of Kentucky (UK) is a public land grant university dedicated to improving people's lives through excellence in education, research and creative work, service, and health care. As Kentucky’s flagship institution of higher education, the university plays a critical leadership role by promoting diversity, inclusion, economic development, and human well-being.

The infrastructure at UK is more than capable of supporting a study of this magnitude. According to the National Science Foundation (NSF) rankings, UK ranked 63rd among public and private universities and 42nd among public universities based on research and development expenditures in fiscal year (FY) 2018. The NSF figures are regarded as one of the most widely accepted measures of research productivity by American universities and colleges. In FY 2019, UK faculty, staff, and students brought in more than $417.1 million in new sponsored project awards. Of that total, UK was awarded $241.8 million in grants and contracts from federal agencies, and has several instrumental resources to support research endeavors. The constellation of programs at UK has enabled the development extraordinarily productive collaborations across diverse disciplines and community. Furthermore, the Carnegie Foundation has selected

UK for inclusion in its 2015 Community Engagement Classification, which recognizes institutions that provide evidence of substantial engagement and contribution to their communities. The designation is the result of a two-year application process and is valid through 2025.

One of the key resources available at UK is the University of Kentucky, Center of Excellence in Rural Health (CERH). Located in Hazard, Kentucky, in the heart of the Appalachian coalfields, CERH was established as an entity responsive to rural Kentucky's health disparities. CERH was established in 1990 by the Kentucky Legislature with a mission to improve the health and wellbeing of rural Kentuckians. CERH strengthens rural communities by making place-based health professions education available in the region, collaborates with rural communities and other stakeholders to develop more effective approaches to rural health service delivery, engages in rural health policy research and provides medical services to residents of Appalachian Kentucky. The Center serves as the federally designated Kentucky Office of Rural Health, providing a framework linking small rural communities with local, state, and federal resources while working toward long-term solutions to rural health issues.

Importantly, the CERH has become a focal site and valuable resource for researchers and students interested in implementing health research in underserved areas, as well as an avenue to connect with community stakeholders, practitioners, and residents. Through the critical community resources available at CERH, UK research teams implement place-based, community-engaged research designed to advance understandings of health disparities in Central Appalachia. Together, the University of Kentucky and CERH have several decades of experience successfully implementing

programs in Appalachian Kentucky. Within the CERH, the UK North Fork Valley Community Health Center operates as a joint venture of the UK College of Medicine and the North Fork Valley Community Health Center board, which serves as a partner organization on this grant. As the first community health center in Kentucky to be affiliated with a university and family medicine residency training program, North Fork provides state-of-the-art facilities and a wide range of services, including a fully equipped clinic consisting of 14 full-size exam rooms, a procedure room, and a dental suite. The clinic, which has fully implemented electronic medical records, is staffed with practitioners in Family and Community Medicine and Primary Care. Additionally, UK is committed to providing equal opportunity all involved with the university, and has a strong anti-discrimination policy (See Appendix A).

Section V: Partnerships and Collaboration

In order to ensure that all aspects of the intervention are inclusive and non-stigmatizing, a community advisory board will be formed to oversee the intervention. The community advisory board will include medical directors from each of the three healthcare organizations, the judge-executive of Perry County, and three members of the community. The medical directors from each of the three healthcare organizations were selected due to their intimate knowledge regarding the processes of their respective organizations. This will aid in adapting a program that is in-line with the needs of each organization. The judge-executive and community members were chosen to ensure that the program is community oriented and to increase the likelihood of community buy-in, thereby increasing response rates to CRC screening. The community advisory board will receive monthly updates by email from the research

team. Additionally, the community advisory board will meet on a quarterly basis to discuss the current progress and next steps.

Section VI: Project Management

VIa: Principal Investigator

Vashisht Madabhushi, MD, MPH will serve as the principal investigator (PI) for this project. He obtained his MD from Ross University, School of Medicine. He completed his general surgery residency at the University of Kentucky, during which time, he also obtained his MPH from the University of Kentucky. Currently, he is an associate professor and practicing surgeon in the Department of General Surgery at UK. His research interests are focused on identifying and eliminating health disparities in rural populations. He has extensive research experience working with the Appalachian Kentucky community in particular. As the PI for this project, he is responsible for ensuring that the grant objectives are met and overall fidelity is maintained. He will also be responsible for setting and maintain the budget, and will be the primary project staff liaison with the community advisory board.

VIb: Project Manager

Projec T. Manager, MPH – Projec T. Manager obtained her MPH from the Harvard T.H. Chan School of Public Health. She has over 8 years of NIH and CDC project management experience. Ms. Manager with report to Dr. Madabhushi and will be responsible for ensuring the completion of day-to-day grant activities. Additionally, she will train and supervise the graduate students in data collection. She will also

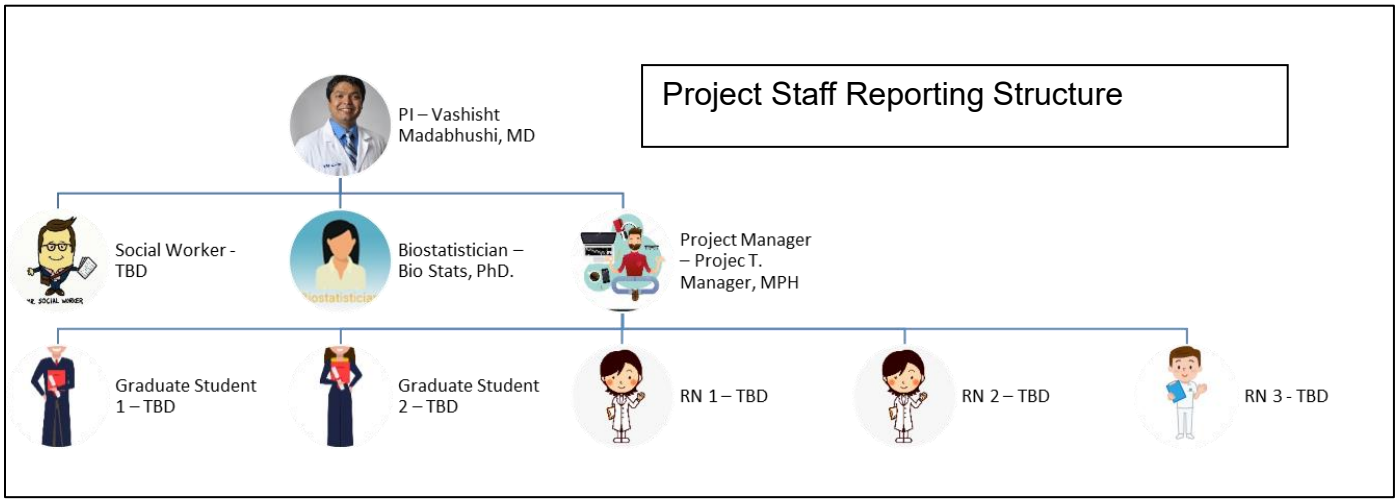
facilitate training of the nurses at each healthcare institution and will conduct random, unannounced observations of these nurses.

VIc: Biostatistician

Bio Stats, PhD, will serve as the primary biostatistician for this project. Dr. Stats is a professor in the Department of Biostatistics in the College of Public Health at UK. She has been instrumental in helping develop project design. She will be responsible for the evaluating if the screening rates of CRC have improved based on this study.

VId: Graduate Students

Graduate Assistants – TBD – 2 graduate students from the College of Public Health at the University of Kentucky will be hired as project staff. On a weekly basis, they will review the Cologuard database and update the list of patients for the nurses, as mentioned above.



Budget and Justification

Personnel

	Effort	Salary	Funded Salary	Fringe	Total
PI	15%	$100,000	$15,000	$4,088	$19,088
	15%	$103,000	$15,450	$4,183	$19,633
	15%	$106,090	$ 15,914	$4,282	$ 20,195
Project Manager	50%	$50,000	$ 25,000	$8,313	$33,313
	50%	$51,500	$25,750	$8,472	$34,222
	50%	$53,045	$ 26,523	$8,636	$35,159
MPH GRA	100%	$32,000	$32,000	$12,800	$44,800
	100%	$32,960	$32,960	$13,004	$45,964
	100%	$33,949	$33,949	$13,214	$47,163
Hazard RN	10%	$50,000	$5,000	$1,663	$6,663
	10%	$51,500	$5,150	$1,694	$6,844
	10%	$53,045	$5,305	$1,727	$7,032
PCCEK RN	10%	$50,000	$5,000	$1,663	$ 6,663
	10%	$51,500	$5,150	$1,694	$6,844
	10%	$53,045	$5,305	$1,727	$7,032
Northfolk RN	10%	$50,000	$5,000	$1,663	$ 6,663
	10%	$51,500	$5,150	$1,694	$ 6,844
	10%	$53,045	$5,305	$1,727	$7,032
Biostatistician	5%	$100,000	$5,000	$1,363	$6,363
	5%	$103,000	$5,150	$1,394	$ 6,544
	5%	$106,090	$5,305	$1,427	$6,732
Year 1					$123,550.00
Year 2					$126,896.50
Year 3					$130,343.40

Vashisht Madabhushi, MD – Principal Investigator (15% effort). Dr. Madabhushi will be responsible for the overall coordination and supervision of all aspects of the study. This includes hiring project managers, coordinating with facilities and clinical nurses, data analysis and management, and maintaining fidelity of the study

Projec T. Manager – Project Manager (50% effort). Ms. Manager will be responsible for the day-to-day activities of the grant, as mentioned above. She will also be the first point person for trouble shooting the grant.

Bio Stats PhD. – Biostatistician (5% effort). Dr. Stats will serve as the biostatistician for this grant. She will review the data collection methods, and be responsible for the interim analysis and final data analysis.

MPH Graduate student x 2 – TBD – (50% effort) – The graduate student will responsible for identifying patients in Cologuard system for contact by clinical nurses. The student will also assist in literature review for publications and review EMR data regarding patient demographics.

Clinical Nurse x 3 – TBD – 10% effort – The nurses will be primarily be responsible for contacting the patients that meet criteria and follow-up with them.

Consultant

	Effort	Salary	Funded Salary	Fringe	Total
Consultant	5.00%	$50,000	$2,500	$831	$3,331
	5.00%	$51,500	$2,575	$847	$3,422
	5.00%	$53,045	$2,652	$864	$3,516

Social Worker – TBD – Up to 5% effort – A social worker from Hazard ARH will be hired as a consultant to assist patients in obtaining insurance coverage and/or improving their accessibility to Cologuard test kits.

Equipment & Supplies

	Price per unit	Number of units	Total Cost
Laptop computer	$ 1,000.00	3	$3,000
Monitors	$ 200.00	6	$1,200
Printer	$ 200.00	1	$200
Stamp Machine	$ 200.00	1	$200
Envelopes	$ 0.05	1500	$75
Postage	$ 0.55	1500	$825
Cologuard Kits	$ -		$10,000

3 Laptop Computers - $1,000 each – One laptop each for the PI, project coordinator, and graduate student to perform grant related activities. Laptops were selected over desktop computers due to the ability to be mobile with the laptops, since all project members will be travelling to the study sites.

6 monitors - $200 each – Two monitors each for the PI, project coordinator, and graduate student to perform grant related activities.

Printer – $200 – Required to print letters to be sent to patients.

Stamp Machine - $200 – Required to place stamps on letters being sent out.

Postage supplies and envelopes - $900 – Required to mail letters to participants

Cologuard Kits for uninsured - $10,000 – Required for patients without insurance coverage

Travel

	Price per unit	Number of units	Total Cost
Mileage – Year 1	$ 0.55	1000	$ 545.00
Overnight – Year 1	$100	9	$900
Mileage – Year 2	$ 0.55	1000	$ 545.00
Overnight – Year 2	$ 100.00	9	$ 900.00
Mileage – Year 3	$ 0.55	1000	$ 545.00
Overnight – Year 3	$100.00	9	$ 900.00
Conferences			
Registration	$350	N/A	$350
Air-travel	$500	N/A	$500
Food allowance	$66	3 days	$198.00
Total Cost for 2 Attendees			$2096

A total of $4335 has been budgeted for the 3 years for travel to and from the healthcare locations for the study staff. Additionally, $2096 has been budgeted for 2 of the study staff to attend a conference at the end of the study period to disseminate our results.

Training

	Price per unit	Number of units	Total Cost
Initial Training			
Hazard ARH RN	8	$23	$184
PCCEK RN	8	$23	$184
Northfork Valley RN	8	$23	$184
Retraining – Year 2			
Hazard ARH RN	5	$23	$115
PCCEK RN	5	$23	$115
Northfork Valley RN	5	$23	$115
Retraining – Year 2			
Hazard ARH RN	5	$23	$115
PCCEK RN	5	$23	$115
Northfork Valley RN	5	$23	$115

$897 has been budgeted for the RN training and potential retraining.

CAB Meetings

	Price per unit	Number of units	Total cost
Quarterly CAB Meetings	$ 150.00	4	$ 600.00

There will be a CAB meeting per quarter and $150.00 has been budgeted for refreshments for each meeting.

	Direct Costs	F&A	Total Per Year
Year 1	$168,978	$89,558	$258,537
Year 2	$157,709	$83,586	$241,294
Year 3	$163,345	$86,573	$249,918
Grant Total			$749,749

Appendix A – University of Kentucky Anti-Discrimination Policy

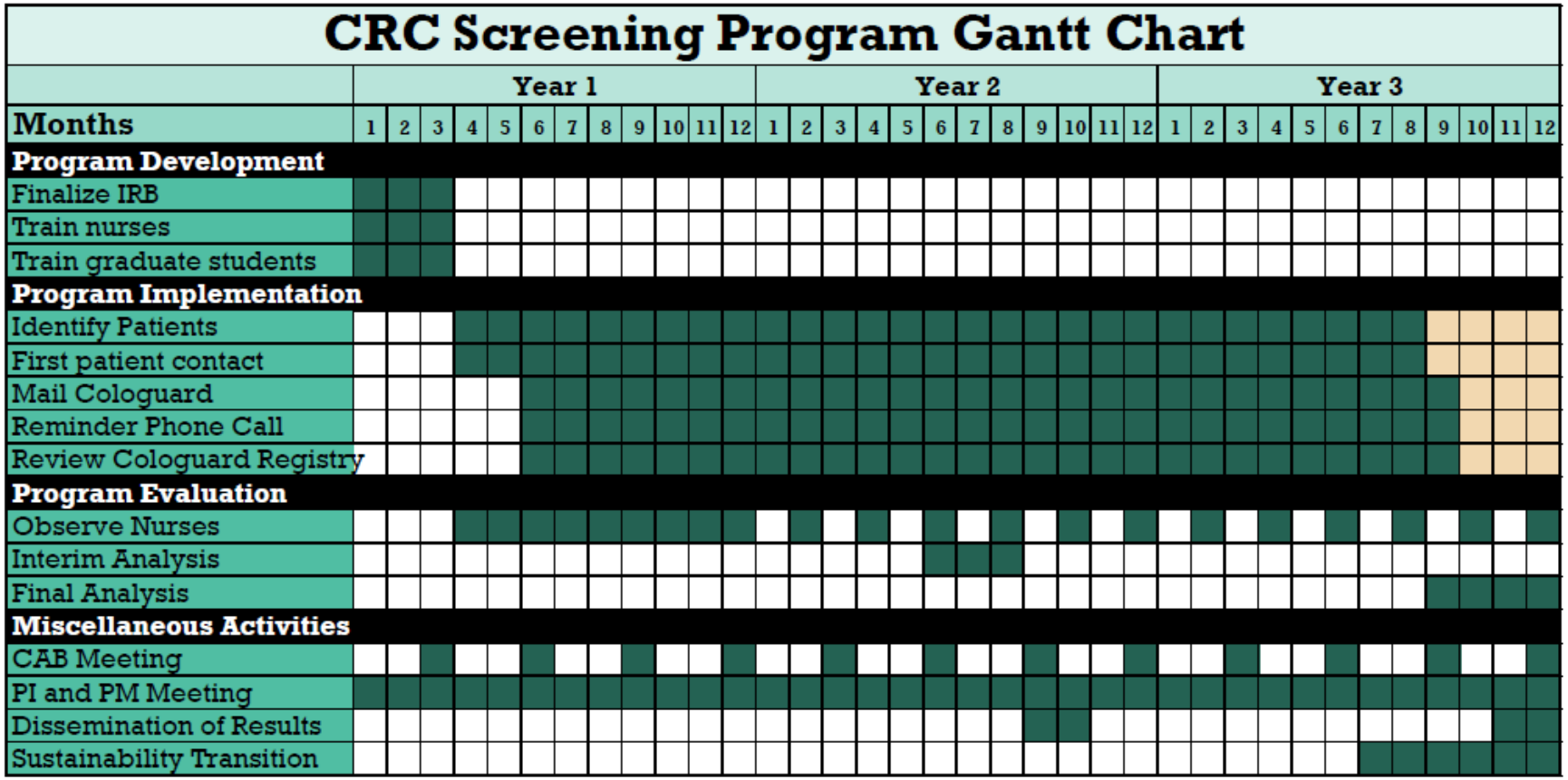
The University of Kentucky is committed to a policy of providing equal employment opportunities to all candidates regardless of economic or social status and will not discriminate on the basis of race, color, ethnic origin, national origin, creed, religion, political belief, sex, sexual orientation, gender identity, gender expression, pregnancy, marital status, genetic information or age. The University does not discriminate against any employee or applicant for employment because of Vietnam-era veteran status, disabled veteran status, or physical or mental disability in regard to any position for which the employee or employment applicant otherwise meets minimum qualifications. The University does not discriminate against any employee or applicant for employment because the individual is a smoker or nonsmoker, as long as the person complies with the University policy concerning smoking. Compliance with Title IX of the Educational Amendments of 1972, which prohibits sex discrimination, and with Title VI of the Civil Rights Act of 1964 is coordinated by the Institutional Equity & Equal Opportunity Office, 13 Main Building, University of Kentucky, Lexington, KY 40506-0032, (859) 257-8927.

Efforts to comply with the laws and regulations applicable to people with disabilities are also coordinated by the Institutional Equity & Equal Opportunity Office, as required by Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990.

The written University of Kentucky Affirmative Action Plan (AAP), in accordance with Executive Order 11246, Section 503 of the Rehabilitation Act of 1973, and The Vietnam

Improving Colorectal Cancer Screening Rates In Perry County

Era Veterans' Readjustment Assistance Act of 1974 (VEVRAA), may be viewed in the Institutional Equity & Equal Opportunity Office. The AAP is available from 9 a.m. until noon and from 1 p.m. until 4 p.m. Monday through Friday when the University of Kentucky is officially in session


CRC Screening Program Gantt Chart
Year 1
Year 2
Year 3
Months
1 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 5 6 7 8 9 10 11 12 1 2 3 4 5 6 7 8 9 10 11 12
Program Development
Finalize IRB
Train nurses
Train graduate students
Program Implementation
Identify Patients
First patient contact
Mail Cologuard
Reminder Phone Call
Review Cologuard Registry
Program Evaluation
Observe Nurses
Interim Analysis
Final Analysis
Miscellaneous Activities
CAB Meeting
PI and PM Meeting
Dissemination of Results
Sustainability Transition

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