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Table Of Contents

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Project Summary

Community health centers (CHCs) do not have the office systems in place to ensure that *every* eligible patient is offered colorectal cancer (CRC) screening. CHCs need evidence-based approaches to implementing office-system changes that take into account the substantial resource, staffing, and time constraints they face. Until this need is met, screening rates will likely remain low, putting thousands of minority, low-income, and uninsured patients at unnecessary risk. The *long-term goal* is to improve CRC screening rates in CHCs and in doing so, reduce cancer health disparities. The *objective of this R21 application* is to test the feasibility of an evidence-informed implementation strategy that combines an office-systems toolkit and outreach education. The *rationale* for the project, supported by preliminary data, is that CHCs want to increase CRC screening rates, but need evidence-based tools that—with training and technical assistance—they can implement and maintain more efficiently and effectively. Although the proposed implementation strategy is evidence-informed and promising, it is novel in the CHC setting and needs to be feasibility-tested in this challenging organizational context prior to larger-scale evaluation. This research study will pursue three *specific aims*: (1) assess the extent of implementation of office-system changes that promote CRC screening, using the CRC toolkit and outreach specialist; (2) estimate the costs of implementing and maintaining office-system changes, using the CRC toolkit and outreach specialist; (3) conduct a limited test of the office-system changes implemented, using the CRC toolkit and outreach specialist. For the first aim, interviews and surveys informed by a conceptual model of innovation implementation will be used to examine the number and type of office-system tools that CHCs implement, the amount and type of outreach support provided, and organizational factors predictive of implementation effectiveness. For the second aim, process maps, activity logs, and unit prices will be used to estimate the cost of implementing changes to the CRC screening process and calculate net benefit by comparing the costs and revenues of CRC screening processes pre- and post-implementation. For the third aim, changes in documented physician recommendation for screening and completed screenings will be assessed through chart audits pre- and post-implementation. This project is *innovative* in that it attempts to shift the current paradigm for making systems-based changes in CHCs from the quality improvement collaborative approach to one that promises greater feasibility given CHCs' resource constraints. *The proposed research is significant* because of its potential to improve public health by increasing CRC screening rates in minority, low income and insured populations and its contribution to scientific knowledge about how the office-systems approach works.

Project Narrative

The proposed project is *relevant to public health* because an effective strategy for implementing office-system changes that uses fewer resources and achieves higher screening rates than current systems-based approaches could lead to the prevention or early detection of thousands of colorectal cancer cases annually among minority, low-income, and uninsured patients. Thus, the proposed research is *relevant to the part of the NCI's mission* to conduct and fund research that improves early detection and diagnosis and reduces cancer disparities.

SPECIFIC AIMS

Colorectal cancer (CRC) screening is effective in preventing or detecting cancer at an early stage. Yet, the patient populations served by community health centers (CHCs) are screened at lower rates than the general population [1-3]. Poor screening rates in CHCs, in turn, contribute to cancer health disparities for minority, low-income, and uninsured patients. It is well established that a physician recommendation is an influential factor in a patient's decision to undergo cancer screening [4-6]. Yet, CHCs do not have office systems in place (i.e., organizational policies and processes such as reminder, tracking, and communication systems) to ensure that every eligible patient is offered screening [7]. Quality improvement collaboratives, the prevailing model for implementing systems-based changes to promote cancer screening in CHCs, have produced encouraging results, but participation places heavy demands on CHCs that are chronically overburdened and under-resourced. Given the substantial increase in patient volume expected when mandatory insurance provisions take effect, an *urgent need* exists for evidence-based approaches to implementing office-system changes that take into account the resource, staffing, and time constraints that CHCs face. Until this need is met, CRC screening rates will likely remain low in CHCs, putting thousands of people at unnecessary risk for CRC.

Our *long-term goal* is to improve CRC screening rates in CHCs and in doing so, reduce disparities in cancer outcomes. The *objective of this R21 application* is to test the feasibility of an evidence-informed strategy for implementing office-system changes in CHCs that promote CRC screening. The strategy combines an office-systems toolkit (adapted from the National Colorectal Cancer Roundtable [8]) and an outreach specialist to provide training and technical assistance. Our *rationale* for the project, supported by preliminary data, is that CHCs want to increase screening rates, but need simple, evidence-based tools that—with training and technical assistance—they can implement and maintain with the time and resources that they have. The strategy we propose is evidence-informed and promising [7, 9-16], but is novel in this setting and therefore needs to be feasibility tested in this challenging organizational context prior to larger-scale evaluation. Our research team has the necessary breadth of expertise and experience (see *Biographical Sketches*), and has access to at least 4 CHCs with 14 clinic sites that are willing to participate (see *Letters of Support*).

We will test the feasibility of the proposed implementation strategy by pursuing the following *specific aims*:

Aim 1: Assess the extent of implementation of office-system changes that promote CRC screening, using the CRC toolkit and outreach specialist. Through key informant interviews and provider surveys, and guided by an organizational model of innovation implementation, we will examine the number and type of office-system tools that CHCs implement, perceived ease or difficulty of implementing office-system tools, amount and type of outreach support provided, perceived quality and usefulness of outreach support, and organizational factors predictive of implementation effectiveness.

Aim 2: Estimate the costs of implementing and maintaining office-system changes, using the CRC toolkit and outreach specialist. Using process maps and monthly activity logs**,** we will estimate the cost of implementing changes to the CRC screening process by tracking resources used during the project, and the net benefit of the new system to the CHC by comparing the costs and revenues of the CRC screening processes pre-implementation to the costs and revenues post-implementation.

Aim 3: Conduct a limited test of the office-system changes implemented, using the CRC toolkit and outreach specialist. We will measure changes in documented provider recommendation for screening and documented screening results through chart audits at baseline and post-implementation.

This project is *innovative* in that it attempts to shift the current paradigm for making systems-based changes that promote cancer screening in CHCs from the collaborative approach to one that promises greater feasibility given resource constraints of CHCs. Consistent with the purpose of the R21 funding mechanism, the *expected outcomes* of the project will provide a solid basis for a larger-scale trial of the implementation strategy. Results from Aims 1 and 2 will indicate which office-system tools the CHCs were able to implement, how much and what type of support they needed, and how much staff time and resources it took to implement office-system changes using this approach. Aim 3 will generate effect-size estimates to inform the development of a larger-scale trial. In addition to advancing implementation science, the project is expected to have a *positive impact* on the health of minority and underserved populations by helping CHCs improve their CRC screening rates.

RESEARCH STRATEGY

1. Significance. Low screening rates in CHCs represent a lost opportunity to reduce CRC mortality and morbidity among minority, low income, and uninsured Americans. Compared to the US population, patients served by community health centers are more likely to be African American (28% vs. 13%) or Hispanic/Latino (33% vs. 15%), have incomes at or below federal poverty guidelines (70% vs. 13%), and have no insurance (38% vs. 15%) [17]. Yet, studies indicate that CHCs screen less than 10 percent of eligible patients for CRC [1-2, 16, 18-20]. In the past decade, the most ambitious initiative to improve cancer screening rates in CHCs has been the Health Disparities Cancer Collaborative (HDCC), sponsored by the Health Resources Services Administration (HRSA), the National Cancer Institute (NCI), and others. Using the Breakthrough Series collaborative model [21] and quality improvement methods to make systems-based changes in care provision, 14 of the 16 CHCs in the HDCC increased their CRC screening rates an average of 4% in 12 months [18]. A later initiative involving 4 CHCs in a regional cancer collaborative achieved a 13% increase in CRC screening rates in 15 months [1]. Both initiatives produced encouraging results, but collaborative participation placed a heavy burden on CHCs, requiring an average of 950 hours of staff time per CHC [1, 18]. For many CHCs, the collaborative approach is impractical given the resource, staffing, and time constraints they face.

The proposed research is significant for its potential to improve public health by increasing CRC screening rates in minority, low income and uninsured populations. An evidence-based strategy for implementing office-system changes that uses fewer resources and achieves higher screening rates than the collaborative approach could help CHCs reach the goal of universal CRC screening. Universal CRC screening in CHCs nationwide would prevent or detect early nearly 16,000 CRC cases annually in patient populations that suffer a disproportionate cancer burden. The need for changes in office systems that ensure consistent screening will grow with mandatory health insurance provisions in 2014. CHCs are expected to see a substantial number of new patients [22], many of whom are not up-to-date on screening. The anticipated expansion of preventive health services coverage reinforces the need for an organized (systems) approach to CRC screening.

The proposed research is also significant for its potential to contribute to scientific knowledge about how the office-systems approach works. The office-systems approach—which combines the provision of tools, training, and technical assistance to make systemic organizational changes in care processes—has been shown to be feasible, acceptable, and, to varying degrees, effective in increasing cancer screening, depression screening, smoking cessation, and other preventive services in a wide range of primary care practice settings [7, 9-16, 23-24]. Yet, the intervention remains a "black box." Published reports often omit important details about which tools are implemented by practices [7, 10, 15, 23], what kind of training or assistance they needed [7, 9-10, 13, 15-16, 23], and at what marginal cost [7, 9-11, 13, 15, 23-24]. Moreover, process evaluation data linking variation in outcomes with variation in either the level or type of training and assistance provided or the extent of office-system changes implemented is often missing [7, 10, 15-16, 23]. By examining these issues, our project is expected to add knowledge that could guide the use of this promising strategy in future studies. What is learned could be useful for increasing screening rates for other cancers and in other primary care settings.

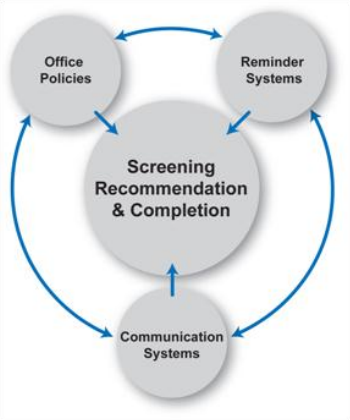
2. Innovation. The proposed project is innovative in that it seeks to shift current approaches to implementing systems-based changes in CHCs from the quality improvement collaborative model, which requires a large, complex, and expensive national (or at least regional) infrastructure and which poses heavy demands on CHCs, to an approach that holds the promise of being more feasible given CHCs' resource, staffing, and time constraints. The use of the office-systems approach for CRC screening in CHCs is itself rather innovative. It has been tried once before in CHCs [7], but with a low-intensity "train-the-trainer" model rather than the usual "direct contact" model found in other studies [7, 9-11, 13-16, 23] *and proposed here*. Given that study's limited results [7], the "train the trainer" model might have been too low-intensity to meet CHCs' needs. Other innovative aspects of the project include the use of organizational implementation theory to guide feasibility assessment, the inclusion of "standing orders" for high sensitivity fecal occult blood tests (FOBT) or fecal immunochemical tests (FIT) as an office policy in the toolkit, and the focus on implementation costs.

3. Approach

3.1. Description of the Implementation Strategy. The implementation strategy that we will test for feasibility combines a toolkit for making office-system changes to support CRC screening and an outreach specialist to provide on-site training and technical assistance. Our CRC toolkit, based on a model developed by the National Colorectal Cancer Roundtable [8], includes simple evidence-based tools to support universal CRC

screening for every eligible patient based on US Preventive Services Task Force (USPSTF) guidelines [25]. The toolkit identifies 3 mutually reinforcing office-system components: (1) office policies for CRC screening that fit the practice, its patients, and local conditions; (2) reminder systems to cue providers and patients to take action; and (3) communication systems to support shared informed decision-making. These components work together to *create a system* in which CRC screening recommendations and follow-up are consistently and universally applied to all eligible CHC patients (see Figure 1). The toolkit was assembled based on a review of research evidence and includes (1) sample policies, algorithms and flow sheets; (2) chart prompts, tracking logs, and reminder systems; and (3) communication scripts, decision aids, and ideas for redistributing staff roles. The outreach specialist will help practices individualize office-system changes from the toolkit, given that simple distribution of new guidelines is not sufficient to increase adherence. She/he will conduct needs assessments, provide education and training, and offer assistance and feedback during implementation. The office-system tools and outreach specialist approaches are evidence-based [7, 9-16, 26-28], but have not been combined and feasibility tested for improving CRC screening in CHCs.

Figure 1. Office-systems Approach to CRC Screening



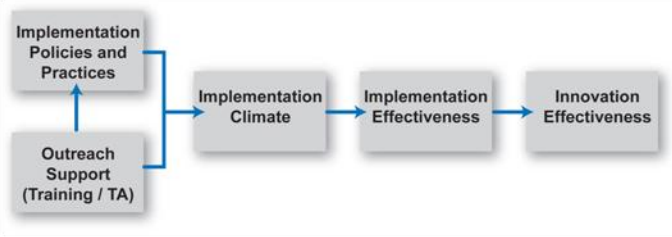
3.2. Preliminary Studies. Our research team has been working with CHCs to increase CRC screening rates for 4 years. We began with formative research to assess the acceptability of a collaborative model similar to the HDCC. In a June 2006 focus group, CHC providers indicated they would be more receptive to an approach involving on-site assistance than to one involving a collaborative model, which they felt was too burdensome. In response, we changed our strategy to one that combines an office-systems toolkit and an outreach specialist (see *Description of the Implementation Strategy*). Using feedback from 2 more focus groups, we reduced the length of the CRC toolkit developed by the National Colorectal Cancer Roundtable from 116 pages to 30 pages and retained only those tools that were deemed appropriate for CHC settings and populations (see toolkit in the *Appendix*). Because CHCs serve many uninsured patients, focus group participants felt that FOBT/FIT was the only feasible approach until colonoscopy becomes affordable for all. Many CHCs have safety net arrangements with local gastroenterologists to perform colonoscopy for patients who have a positive stool test. We have negotiated similar arrangements in other studies involving safety-net health care providers (U01CA114629).

We held a fourth focus group in June 2010 to assess acceptability of the revised CRC toolkit and gather more information about the level and type of outreach support desired. Providers wanted the outreach specialist to become familiar with current cancer screening practices in each clinic so that she/he could help them select, modify, and implement tools that complemented existing systems. Larger clinics wanted their own staff to handle more implementation tasks, while smaller rural clinics wanted to allocate most tasks to the outreach specialist. They advised hiring an outreach specialist with experience in public health clinic settings and electronic medical record (EMR) systems. Focus group participants noted an acute need for tools and technical assistance to improve follow-up on distributed FOBT/FIT kits. There was strong interest in using FIT because of its fewer medication and dietary restrictions and newer tests that only require returning one sample. All endorsed the project and offered to serve as advisors or participants.

3.3. Conceptual Model. We use as a guide for this study a simplified version of an organizational model of innovation implementation that we have developed in prior work (see Figure 2)[29-30]. An *innovation* is an idea, technology, or practice that an organization uses for the first time [31-34]. Briefly, our model posits that effective implementation (i.e., consistent, high-quality innovation use) is a function of (a) the policies and practices that an organization employs to support innovation use (i.e., office-system tools), (b) the training and technical assistance the organization receives from the outreach specialist, and (c) the implementation climate that results from these factors (i.e., staff members' shared perceptions that innovation use is expected, supported, and rewarded). Innovation effectiveness (e.g., improved screening rates, costs) depends on effective implementation. Training and technical assistance from the outreach specialist is expected to support the implementation of office-system tools and strengthen the implementation climate by, for example, increasing providers' knowledge and skills and reinforcing the priority of the implementation effort.

3.4. Recruitment and Enrollment of Community Health Centers. North Carolina has 26 CHCs delivering services in 120 clinic locations to nearly 400,000 patients, 70% of whom live below the federal poverty level, half of whom are uninsured, and 23% (~75,000) of whom are age 50 or older [35]. We will recruit 5 individual CHC clinics with assistance from Marti Wolf, Clinical Programs Director of the North Carolina Community Health Center Association (see *Biographical Sketch*). Ms. Wolf is a trusted source of information and has recruited CHCs for other research projects. Ms. Wolf will present the proposed project during monthly conference calls with CHC leaders, and the research team will follow up with those CEOs and Medical Directors who express interest in participating. We will apply 3 eligibility criteria. First, clinics must be located within a 2-hour driving distance of Morrisville, NC, where the outreach specialist will be housed so she/he can maintain frequent contact with the clinics. Second, clinics must have an EMR system, so that data collection is more efficient. Third, clinics must identify a "project champion" to work with the outreach specialist and serve as the primary contact person for the research team. Twenty clinics meet the first 2 criteria. We will recruit 5 clinics and 1 back-up clinic in case a site drops out during the early phase of the study. Based on feedback from our focus groups, interest in participating is high and we have letters of support from 4 CHCs which have 14 individual clinic sites.

Figure 2. Organizational Model of Innovation Implementation



3.5. Study Procedures. During the first six months, the PI and research team will meet with the Medical Director, CEO and project champion at each clinic to review participation requirements, discuss project logistics, and assess EMR capabilities. The PI and research team will hire and train an outreach specialist with experience in clinical research, quality improvement, and EMR systems. The outreach specialist will spend two months (Months 6-7) meeting with project champions, observing clinic operations, and conducting needs assessments. The assessment will involve: 1) a practice environment checklist to inventory current office-system capabilities and CRC screening processes, and 2) semi-structured interviews with clinical and administrative key informants to supplement the checklist data and determine training and technical assistance needs. After the research team analyzes the needs assessment data, the outreach specialist will meet with clinic providers and staff to discuss gaps in the clinic's current CRC screening processes, and present office-system options from the toolkit.

Starting in Month 8, the outreach specialist will work with the project champion and other staff members in each clinic to select, modify, and implement tools from the three mutually reinforcing toolkit components (i.e., office policies, reminder systems, and communication systems). Each clinic will receive outreach support for ten months (Months 8-17). Based on our experience with an earlier outreach support intervention [36], the amount of time that the outreach specialist will need to spend in each clinic will range from 4 to 6 hours every other week. We will adjust the number, frequency, and duration of outreach visits based on feedback from the outreach specialist and clinic staff. As is common in office-system studies, the purposes of outreach visits will vary over time and across clinics, but will include staff training and re-training, practice audits and feedback, problem identification and brainstorming, and provision of materials and resources. In this project, the CRC toolkit will establish the training content. Performance feedback will be delivered as clinics incorporate CRC screening forms into their EMR system and begin to systematically document screening recommendations and results. New "meaningful use" criteria for EMR should facilitate this effort (M. Wolf, personal communication). The outreach specialist and data analyst will generate reports and create run charts to illustrate providers' progress in completing standing orders for FIT and tracking follow-up rates for CRC screening. The outreach specialist will participate in staff meetings to share performance data, review strategies, discuss barriers, and update educational materials and other resources for CRC screening.

3.6. Data Collection Methods. We will assess feasibility using data from several sources (see Table 1).

Checklist. We will use a checklist adapted from prior studies [11, 13] to inventory the office-system tools in place and the CRC screening process in the CHC (e.g., identification, recommendation, screening, follow-up, results reporting, and referral) pre- and post-implementation (Months 6-7 and Months 18-20).

Outreach Logs. On a monthly basis during implementation (Months 8-17), the outreach specialist will enter data on the number, frequency, duration, and purpose of each clinic contact into an MS Access database. In each clinic contact, she/he will query the project champion about the amount of staff time (e.g., person hours) and other resources the CHC has expended in support of implementation since the last clinic contact.

Table 1. Theoretical Constructs, Measures, Data Sources, and Data Collection Timing

Construct	Measures	Source	Timing
Implementation Policies and Practices	Number and type of office-system tools put into place Perceived ease or difficulty of implementing office-system tools	Checklist Interviews	Pre- and Post-implementation Post-implementation
Outreach Support (Training and Technical Assistance)	Number, frequency, and duration of outreach contacts Contact purpose (e.g., training, practice audit, problem-solving) Quality of outreach specialist technical assistance	Outreach logs Outreach logs Interviews	Implementation Implementation Post-implementation
Implementation Climate	Implementation climate instrument Provider intent to continue using office systems for CRC screening	Provider survey Provider survey	Post-implementation Post-implementation
Implementation Effectiveness	Documented clinician recommendation or standing orders for CRC screening Frequency and quality of office-system tool use	Medical records Interviews	Baseline (T+3) and Post-implementation Post-implementation
Innovation Effectiveness	Documented results of completed CRC screening	Medical records	Baseline (T+3) and post-implementation
Implementation costs	Resources associated with CRC screening process Resources expended in implementation process Unit prices of resources	Checklist Outreach logs Market prices	Pre-and Post implementation Implementation Post implementation

Provider Survey. We will administer a web-based survey post-implementation (Months 18-20) to obtain data about implementation climate and intent to continue using office systems for CRC screening. The survey sample will consist of 5-10 individuals per clinic (N = 25-50). Sample size will vary due to clinic differences in the number of providers and staff. We will develop climate measures from existing surveys [37-39]. We will use evidence-based strategies to increase response rates for our web-based provider surveys such as (1) using short, personalized email communications; (2) offering to share the study results; (3) sending reminders; and (4) giving a deadline [40]. Because implementation climate is an organization-level construct, we will test whether sufficient within-group agreement exists to aggregate individual responses to the clinic level [41-42]. If tests do not justify aggregation, we will examine intra-clinic variability in climate perceptions [41].

Medical Records. We will obtain data on documentation of screening recommendation or standing orders (implementation effectiveness) and results of completed screening tests (innovation effectiveness) through cross-sectional reviews of randomly chosen medical records of eligible patients at baseline (Months 8-9) and post-implementation (Months 18-19). At baseline, we will ask each clinic to generate a list of patients ages 50 to 75 years with at least 1 clinic visit in the past 13 months. We will then select a random sample of records for review from each clinic. To account for variation in clinic size, the number of records selected will be 20 times the number of physicians in the clinic, up to a maximum of 140 records (N=700) in clinics with 7 or more physicians [11]. Our trained research assistant will determine if the patient was eligible at the time of the clinic visit for a CRC screening recommendation (i.e. not up-to-date according to PHS guidelines). If the patient was eligible for a recommendation, she will then record: 1) is there documentation of a recommendation or standing orders? (yes/no), and 2) is there documentation of screening test results? (yes/no). Like other studies, we will use a 3-month grace period to allow patients sufficient time to complete a recommended screening[11,16]. This means the observation period for screening recommendation is 10 months and the observation period for results of completed screening is 13 months. To make the post-implementation observation periods equal to the baseline observation periods, we will count screenings recommended in Months 18-19 as complete if charts show documentation of results through Months 21-22. At least 10% of charts will be reviewed for at least one clinic by a separate member of the UNC research team for quality assurance purposes.

Interviews. We will conduct semi-structured interviews post-implementation (Months 18-20) with 4 to 6 key informants per clinic (N=20-30) including Medical Director, project champion, and 2 to 3 other providers. These interviews will help us obtain data about implementing office-system changes using the CRC toolkit (implementation policies and practices) and about satisfaction with the amount and quality of outreach support provided (outreach support). These qualitative data will supplement the quantitative data collected in the provider survey. Interviews, each lasting about 30 minutes, will be digitally recorded with permission, transcribed verbatim, and coded by two research team members using ATLAS.ti and a codebook based on the conceptual framework (see Figure 2).

3.7. Feasibility Assessment. We will assess the feasibility of the proposed implementation strategy using a one-group, pre-post study design. This study design is suitable for exploratory/developmental research (R21)

and commonly used in feasibility studies [43]. Assigning all CHCs to the "implementation group" maximizes the information yield about which office-system tools they were able to implement; how much and what type of support they needed; the level of resources required to implement office-system changes using this approach; and how variation in office-system changes relates to variation in CRC screening outcomes.

3.7.1. Aim 1: Assess the extent of implementation of office-system changes that promote CRC screening, using the CRC toolkit and outreach specialist.

Purpose. The proposed implementation strategy, while evidence-informed, has not been tried in CHCs (see *Innovation*). Before proceeding to a larger-scale test, we need to know: can CHCs implement office-system changes using this approach and, if so, how much and what kind of training and technical assistance do they require? The *objective of this aim* is to answer these feasibility questions [43]. The *working hypothesis* is that with outreach support, CHCs can implement tools from the 3 mutually reinforcing toolkit components (i.e., policies, reminder systems, communication systems) and, in doing so, create a implementation climate that promotes consistent CRC screening recommendation (i.e., effective implementation). We are prepared to examine an alternative hypothesis that partial office-system changes (i.e., omission of one or more mutually reinforcing toolkit components) is sufficient to create a positive climate and promote effective implementation.

Data Analysis. We will use visual plots and non-parametric tests (e.g., Spearman's correlation) to examine the associations between the clinic-level measures of: (1) outreach support and implementation policies and practices; (2) these variables and implementation climate; and (3) implementation climate and implementation effectiveness. We will use qualitative data about perceived ease or difficulty of implementing office-system tools and perceived quality of outreach support to explore in more detail the patterns we observe in the quantitative data. We will use descriptive statistics to examine which office-system tools the CHCs were able to implement and how much and what type of support they needed.

3.7.2. Aim 2: Estimate the costs of implementing and maintaining office-system changes that promote CRC screening, using the CRC toolkit and outreach specialist.

Purpose. Before adopting a new approach or expanding current CRC screening activities, CHCs will want to know the cost of implementing the changes. The *objectives of this aim* are to estimate the resources required to implement changes to current CRC screening processes and estimate the net benefit (or cost) of the new CRC screening approach using a resource-based costing approach. The *working hypotheses* are that: (a) implementation costs will be greater for CHCs with no office systems in place than for those CHCs with some office systems in place (e.g., policies but no reminder systems); (b) there are increasing economies of scale associated with increased screening activities; and (c) net benefit increases with scope of screening activities.

Data Analysis. We will identify the resources associated with each stage of the CRC screening process or implementation activity and apply a unit price to each resource. The net benefit [(ScreeningRevenusPre – ScreeningCostsPre) - (ScreeningRevenuesPost – ScreeningCostsPosts)] of each CHC's CRC screening process will be assessed by comparing the resources associated with CRC screening pre- and post-implementation, and the change in revenues generated from the increased activity. The practices will be provided with the estimate of the additional resources required/saved, the unit prices assigned to each resource and the total estimated cost/savings. The revenue from the additional screening will be the number of individuals screened multiplied by a reimbursement rate (e.g., Medicaid). One-way sensitivity analysis will be performed on key parameters to provide estimates of the costs and benefits (e.g., revenues and number of people screened) to the clinic. The resources associated with implementation will be calculated by comparing the resources required in implementation (e.g., software installation) with those identified in the pre- and post-checklists. One-way sensitivity analysis will examine the robustness of results to changes in key parameters.

3.7.3. Aim 3: Conduct a limited test of the office-system changes implemented, using the CRC toolkit and outreach specialist.

Purpose. Evidence that office-system changes improve CRC screening rates in CHCs is lacking (see *Innovation*). Before proceeding to a larger-scale test, we need to know: does this implementation strategy show promise in increasing CRC screening rates in this organizational setting, and, if so, how much of an effect could we expect to see in a larger study? The *objective of this aim* is to answer these feasibility

questions [43]. The *working hypothesis* is that increasing the provider screening recommendation rate (implementation effectiveness) in turn increases the screening completion rate (innovation effectiveness).

Data Analysis Strategy. We will measure changes in the proportion of eligible audited charts with documented recommendation for CRC screening and documented screening results at baseline (Months 8-9) and follow-up (Months 18-19, see *Medical Records* section above). We will compute percentages for all clinics, as well as for individual clinics, and use Fisher's exact test to detect significant differences pre- and post-intervention.

3.8. Potential Problems and Alternative Approaches. Even with outreach support, some clinics might experience implementation difficulties. Assessment of the extent of, facilitators of, and barriers to successful implementation will inform a larger-scale trial. It is possible that clinics will make only modest improvements in screening recommendation and completed screening rates over a 10-month period. Other studies have used a 12-month period and reported significant changes [11, 16]. Finally, it is possible that we will encounter low or variable survey response rates. Our research team has experience conducting provider surveys and we will develop a working relationship with each clinic. If this problem were to arise, we would use measures of within-group agreement for implementation climate that account for variable response rates and missing data [41].

3.9. Timetable. Table 2 summarizes our proposed timeline for project activities.

Table 2. Timetable for Project Activities

Pre-Implementation Phase (7 months)	**Timing**
Submit initial IRB application; develop and post educational outreach specialist position (*research team*)	Months 1-2
Recruit 5 clinics and identify project champions (*research team*)	Months 1-3
Finalize data collection forms and survey instruments; obtain final IRB approval (*research team*)	Months 3-4
Make introductory site visits to 5 participating clinics to introduce study (*research team*)	Months 4-5
Hire and train educational outreach specialist (*research team*)	Months 4-5
Meet with clinic staff and office champion; conduct needs assessment including office systems inventory (*outreach specialist*)	Months 6-7
Analyze needs assessment data (*research team*)	Months 6-7
Implementation Phase (10 months)	
Report needs assessment results to clinics and initiate training and implementation of CRC toolkit (*outreach specialist*)	Months 8-9
Incorporate screening documentation into EMR systems (*outreach specialist*)	Months 8-9
Conduct baseline medical record audit for % of charts documenting 1) provider recommendation or standing orders for CRC screening; 2) results from completed screening*(research assistant*)	Month 8-9
Provide ongoing technical assistance based on individual clinic needs (*outreach specialist*)	Months 8-17
Collect process evaluation data and services delivered using outreach specialist log (*outreach specialist*)	Months 8-17
Post-Implementation Phase (7 months)	
Conduct follow-up medical record audit for % of charts documenting 1) provider recommendation or standing orders for CRC screening; 2) results from completed screening (*research assistant*)	Months 18-19
Conduct office-systems inventory (*outreach specialist*), provider surveys (*web-based*), and interviews *(qualitative analyst*)	Months 18-20
Analyze process and outcome evaluation data and calculate cost of intervention (*research team*)	Months 21-22
Study closure: initiate journal articles and R01 grant application for randomized trial	Months 23-24

3.10. Future Directions. At the conclusion of this project, we expect to have demonstrated the feasibility of an evidence informed strategy for implementing office-system changes in CHCs that promote CRC screening. The next logical step in our program of research would be to test the implementation strategy on a larger scale over a longer duration. We would contemplate seeking R01 funding to conduct a practical [44-45] group-randomized trial in which we recruit a heterogeneous sample of CHC clinics in North Carolina, randomize them into intervention and control conditions, switch the control clinics to the intervention condition at the first follow-up period, and assess multiple relevant outcomes such as implementation fidelity, innovation effectiveness (screening rates), durability (at both clinic and patient level, i.e., repeat screening), and implementation and maintenance costs. The larger-scale test would also provide HRSA and primary care associations with more detailed information about the costs of scaling up and sustaining the toolkit and outreach specialist approach.