

## Specific Aims Example – Clinical Implementation

### A. 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.