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Rationale and design of Mi-CARE: The mile square colorectal cancer screening, awareness and referral and education project

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ABSTRACT

Although colorectal cancer (CRC) is largely preventable through identification of pre-cancerous polyps through various screening modalities, morbidity and mortality rates remain a challenge, especially in African-American, Latino, low-income and uninsured/underinsured patients. Barriers to screening include cost, access to health care facilities, lack of recommendation to screen, and psychosocial factors such as embarrassment, fear of the test, anxiety about testing preparation and fear of a cancer diagnosis. Various intervention approaches to improve CRC screening rates have been developed. However, comparative effectiveness research (CER) to investigate the relative performance of different approaches has been understudied, especially across different real-life practice settings. Assessment of differential efficacy across diverse vulnerable populations is also lacking. The current paper describes the rationale and design for the Mile Square Colorectal Cancer Screening, Awareness and Referral and Education Project (Mi-CARE), which aims to increase CRC screening rates in 3 clinics of a large Federally Qualified Health Center (FQHC) by reducing prominent barriers to screening for low-income, minority and underserved patients. Patients attending these clinics will receive one of three interventions to increase screening uptake: lay patient navigator (LPN)-based navigation, provider level navigation, or mailed birthday CRC screening reminders. The design of our program allows for comparison of the effectiveness of the tailored interventions across sites and patient populations. Data from Mi-CARE may help to inform the dissemination of tailored interventions across FQHCs to reduce health disparities in CRC.

1. Introduction

As the third leading source of cancer deaths among men and women in the United States, colorectal cancer (CRC) remains an urgent public health challenge [1]. Among solid tumor cancers, CRC is the only cancer that is preventable with the identification and removal of pre-cancerous polyps [2]. Current screening recommendations for individuals at average risk for CRC include timely screening using one or a combination of the following tests [3]: Colonoscopy (every 10 years), Flexible sigmoidoscopy (every 5 years), Double-contrast barium enema (every 5 years), CT colonography (virtual colonoscopy) (every 5 years), High-Sensitivity Guaiac-based Fecal Occult Blood Test (FOBT) (every year), Fecal Immunochemical Test (FIT) (every year), or Stool DNA Test (every 3 years).

Despite the potential to prevent an estimated 90% of CRC deaths through screening [4], screening utilization is low and disparities across sociodemographic and racial/ethnic groups exist [5–8]. Specifically, population-level screening rates for CRC are lower for Latino patients as compared to Whites; socioeconomic status partially explains this disparity [9]. Additionally, incidence and mortality from CRC are highest in African-Americans [1]. Identified barriers to screening include cost, access to health care facilities, insurance status, lack of recommendation to screen [10], and psychosocial factors such as knowledge regarding test preparation, fear of the test and cancer diagnosis, and embarrassment [3]. There is reason to suggest that these barriers may be adequately addressed through effective interventions at institutional and individual levels.

Given the sociodemographic and racial/ethnic disparities in CRC rates, it is essential to develop and implement programs to reduce barriers to screening in clinical settings that serve individuals at highest risk. Patient navigators, individuals who work with patients to educate and assist them in obtaining care, can help facilitate uptake of medical screening [11]. Several studies have investigated the effectiveness of various patient navigation interventions to increase CRC screening uptake among underserved patient populations and have found positive results [12–24]. Despite the positive results of these studies, relatively few have taken a comparative effectiveness research (CER) approach [25,26]. Extant work has largely focused on comparing navigation to mailed reminders. Nonetheless, patient navigation literature suggests there may be differences in efficacy between health professional

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(e.g., nurses, providers) and lay navigators [27,28]. Further, most CRC screening interventions [12] and CER studies do not assess how effectiveness varies across diverse vulnerable populations nor diverse practice settings [29].

The current paper describes the rationale and design for the Mile Square Colorectal Cancer Screening, Awareness and Referral and Education Project (Mi-CARE). The purpose of Mi-CARE is to increase CRC screening uptake in 3 Federally Qualified Health Center (FQHC) clinics serving primarily African-American, Latino, low-income and uninsured/underinsured patients. The primary aim of this project is to compare the relative effectiveness of three CRC navigation interventions on whether patients complete their CRC screening either through return of their Fecal Immunochemical Test (FIT) or completed colonoscopy exam. Specifically, Mi-CARE will compare patient navigation delivered by: 1) lay patient navigator (LPN); 2) provider navigator; and 3) mailed birthday CRC screening reminders to 4) a control group for uptake of CRC screening. The second aim of this project is to determine effect modifiers in different patient populations on CRC screening uptake, with a focus on patient and facility level characteristics. Mi-CARE may provide a model for improving screening services offered through FQHCs providing care to underserved populations.

2. Methods

2.1. Intervention setting

Miles Square Health Center (MSHC) is an FQHC with 13 total clinics affiliated with the University of Illinois Hospital and Health Science System (UIHHSS) in Chicago, IL. As a FQHC, MSHC is able to provide affordable CRC screening for low-income patients addressing a prominent barrier to CRC screening. According to the Department of Health and Human Services, MSHC uninsured rates are consistent with the national average for FQHCs and were last estimated at 27.9% in 2014 (Health Center Data, 2014). In 2015, MSHC patients had a racial/ethnic breakdown consisting of 68.0% African-American, 26.7% Latino, and 5.3% Other.

Three sites (Sites A, B, and C) have been selected based on the volume of patients in the target age range for CRC screening and higher rates of minority patients within the catchment areas according to a recent analysis of Chicago ward level data from Illinois State Cancer Registry (ISCR) and Chicago Department of Public Health (CDPH; Illinois Specific Statistics, 2014). The ethnic breakdown of each site is as follows: Site A is 78.8% African-American, 16.4% Hispanic, and 8.8% Other; Site B is 95.1% African-American, 2.4% Hispanic, and 2.5% Other; and Site C is 20.6% African-American, 70.6% Hispanic, and 8.8% Other. At an average of 62.6 and 59.5, the incidence rates of the Site A and Site B catchment areas are much greater than the national and state rates of 43.9 and 50.2 (Illinois Specific Statistics, 2014), respectively.

2.2. Study participants

Patient participants will be identified using Electronic Health Records (EHR) at each facility. Eligibility criteria are as follows: 1) ages 50–75 years old and 2) scheduled for a provider visit at one of the three participating sites during the 12 month recruitment period. Control patients will also be identified using the EHR and will include patients 50–75 years of age seeking care at MSHC the year prior to implementing the Mi-CARE intervention. Patients will be excluded if their CRC screening is up to date.

2.3. Interventions

Mi-CARE is a quasi-experimental trial in which patients at the selected MSHC locations will receive one of three types of intervention (16.7% to each arm or 50% overall) or serve as a control (50%). Due to programmatic requirements, sample sizes for intervention and control groups were specified prior to implementation, based on the number of potentially eligible patients in a given calendar year for each of the sites. Accordingly, all eligible patients from the year prior to implementation will be designated as "controls" ($n = 1250–1500$). The year of implementation, 416–500 patients will be assigned to each intervention group (LPN, provider navigation, mailed birthday reminders). Patients will be assigned to a particular navigation intervention based on the availability of the LPN at the time of the appointment. It is possible that patients may receive mailed reminders and one of the in-person intervention strategies. These patients will be readily identified via EHRs and will not be included in the current study's analytic sample. The study has been approved by the University of Illinois at Chicago's Institutional Review Board and the MSHC Patient Advisory Board. A description of the interventions and the control condition are described below.

2.3.1. Interventionist identification and training

For the lay patient navigation intervention, MSHC administration has identified two LPNs to implement the Mi-CARE intervention, one of whom is bilingual in Spanish. Both LPNs have had extensive clinical and patient-provider experience within MSHC settings. Each clinic has a LPN present two days/week. For the provider navigation, MSHC administration has identified 14 providers to implement the Mi-CARE intervention, 5 of which were bilingual in Spanish.

All interventionists will undergo computer/online or in-person trainings, based on interventionists' availability. Trainings will be adaptations of modules developed by the ACS pertaining to CRC education and awareness, shared decision making, and motivational interviewing (ACS, 2016; Matthews, Baldwin, & Hannon, 2009). For the provider navigation, the three sites will have one "provider champion" identified to promote CRC screening uptake at each site. The 2 modules will be 20–30 min in length. One module will focus on CRC screening guidelines, tests, and CRC risk factors, onset, symptoms, treatment, and prognosis. The second module will focus on motivational interviewing, including stages of change and shared decision making.

2.3.2. Lay patient navigation (LPN)

A navigation protocol has been created with assistance from the UIHHSS gastroenterology clinical department and Chief Medical Officer of MSHC to provide culturally tailored education and navigation. Components of the navigation protocol include navigation flowchart to colonoscopy/FIT for both insured and uninsured patients, contact list of personnel in the gastroenterology and colon and rectal surgery departments, ACS education materials on CRC in English and Spanish, instructions for FIT, and instruction for colonoscopy preparation (e.g., Golyte prep and dietary instructions for colonoscopy). The LPNs will identify patients through three methods: weekly reviews of provider schedules, provider request, or patient request. The LPNs will see patients either prior to or following their medical appointment. During the in-person encounter, the LPNs will provide education and motivational interviewing regarding uptake of CRC screening. The LPN will then use shared decision making to allow the patient to choose between the FIT or colonoscopy as a method of CRC screening. Once the patient chooses a screening method, the LPN will work with patient's provider to order and schedule a colonoscopy or order a FIT test. For patients selecting the FIT, the LPN will follow up within 14 days for FIT return. For patients selecting a colonoscopy, the LPN will follow up with patient by phone every 14 days until the scheduled colonoscopy is completed. If the patient fails to respond after 3 call attempts, they will be deemed lost to follow-up. Fig. 1 details the patient flow through the LPN intervention.

2.3.3. Provider navigation

The providers at each site will also be supplied with pamphlets in both English and Spanish to assist in guiding the shared decision making discussion on preferred CRC screening method. Once the provider identifies the preferred method of screening, a referral will be provided for