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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.

Keywords

Colorectal cancer; Health disparities; Screening; Federally qualified health center

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

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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 (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 FIT or colonoscopy. Fig. 2 details the patient flow through the provider navigation intervention.

2.3.4. Mailed birthday reminders—Patients receiving the mailed birthday reminders will be selected from patients at the three sites and will have had one patient visit during the recruitment year. The LPNs will mail an ACS postcard reminder to schedule or request a CRC screening. Specifically, the postcard will encourage patients to speak to their provider or call the LPN to discuss getting screened for CRC. Reminder cards will be sent around the patient's birthday.

3. Outcome assessment

The primary outcome for this study is uptake of CRC screening (yes or no) within 12 months of the intervention. This outcome will be assessed by reviewing the EHRs at each facility and determining if colonoscopy or FIT was completed. To determine the impact of the interventions on CRC screening uptake, a database will be developed that will include all patients ages 50–75 who completed at least one patient visit in MSHC during the recruitment year. The following information will be extracted from the EHRs: 1) age; 2) race/ethnicity; 3) insurance status; 4) type of one-on-one navigation (LPN, provider navigation, mailed birthday reminder or none); 5) date navigation was administered (LPN or provider navigation; if applicable); 6) date mailed birthday reminder was sent (if applicable); 7) patient full address, including zip code; 8) date FIT given to patient; 9) date FIT returned; 10) date colonoscopy scheduled; 11) date colonoscopy completed; 12) FIT result; 13) screening colonoscopy result; 14) diagnostic colonoscopy date; 15) diagnostic colonoscopy date; 16) cancer diagnosis date; 17) provider name; and 18) clinic site. The administrative censoring date for all unfinished patients will be the date of study completion.

Neighborhood-level socioeconomic indicators and racial/ethnic composition will be abstracted at the zipcode level using American Community Survey data. Socioeconomic indicators include: percentage of female-headed households, percentage of residents with less than a high school education, percentage of unemployed residents, and percentage of residents at the 100% of the federal poverty level. Racial/ethnic composition will include the proportion of residents who identify as White, African American, and Latino. For all variables, tertiles will be calculated.

4. Proposed analytic plan

For our primary outcome, we will conduct multivariable logistic regression models to examine the effectiveness of the three intervention approaches relative to standard controls in terms of uptake of CRC screening (yes/no). Given our interest in examining multiple intervention groups to the control, we will apply Dunnett's test [30]. Second, multiple effect modification analyses will be conducted to examine interactive effects by 1) race/ethnicity; 2) clinic site; and 3) neighborhood factors (concentrated disadvantage and racial/ethnic composition). Given the sample size for groups are constrained, as described above, we provide the minimum detectable effect size (MDES) [31]. We note that MDES is preferred over sample size requirements, when data have already been collected or when resources are

limited for expensive data collection. Under these circumstances, we describe the smallest true impact the interventions could have, given our programmatic requirements. Using G*Power 3.1.9.2 [32], we calculated the MDES for multivariable logistic regression models for each of the intervention groups, assuming the minimal $n = 1666$ (1250 controls; 416 intervention); wherein 25% of the sample would have received one of the interventions ($p1$); $\alpha = 0.05$; and, power = 0.80. These analyses showed that the MDES odds ratio for a single main effect would be 1.17. MDESs were 1.17, 1.18, 1.19, 1.21, and 1.25 when assuming covariates (including other main effects) explaining 0.05, 0.1, 0.2, 0.3, and 0.5 of the variance, respectively. We note that the MDESs are all smaller than the effects observed in previous, similar CRC interventions ($OR = 1.6\text{--}2.35$) [12,20,22,23]. Relatedly, we anticipate that the difference in uptake of CRC screening between interventions and control groups will range between 14–45 percentage points [12–14,17,20,22–24].

As described above, Mi-CARE is not a randomized study. Given this, there is a need to attempt to reduce potential selection bias that may be introduced by the lack of randomization (e.g., due to navigator judgment). Given this, once data are collected, we will first review descriptive contingency tables with regard to the effect modifiers (race/ethnicity, clinic site, neighborhood factors) across control, LPN, provider navigation, and mailed birthday reminder patients. If there are statistically significant differences in effect modifiers among the four groups, we will employ probability of treatment weighting (IPTW) with propensity scores in sensitivity analyses. In line with best practices [33], we will first compare in the weighted scores the proportions of effect modifiers across groups as well as the interaction effects. Relatedly, Mi-CARE is designed such that an individual may experience multiple interventions (i.e., mailed birthday reminder + LPN/provider navigation). When data are available, we will examine the relative number of patients experiencing both types of interventions. If there is relatively little overlap, we will exclude patients who experienced multiple interventions in our primary analyses. If there are a significant number of patients who have experienced multiple interventions, analyses will be refined, such that multivariable logistic regression models will examine the receipt of CRC screening among control, mailed birthday reminder, LPN, provider navigation, and “multiple intervention” patients.

5. Discussion

CRC mortality rates are high [1] and screening rates are low, particularly among low-income and underserved populations [5–8]. Previous intervention studies are limited by 1) only comparing LPN intervention to a standard care control; 2) having a limited sample that did not allow for comparison across African-American and Latino patients; 3) utilizing only one clinic for the intervention; and 4) lacking a comparison intervention group. The purpose of Mi-CARE intervention is to test the relative effectiveness of three CRC screening uptake interventions – LPN-based navigation, provider navigation, and mailed birthday CRC cancer screening reminders compared to a control group– on whether patients complete their CRC screening either through return of their FIT or completed colonoscopy exam. Additionally, we will test for effect modifiers in different patient populations and clinics on CRC screening uptake. One potential limitation of Mi-CARE is that it is not a randomized controlled trial (RCT), so if differences in screening rates exist based on navigation type, it

will be difficult to determine how the non-randomized selection of the intervention for each patient might have impacted this effect. However, a strength of this design is its ability to be tailored by patient and clinic. A limitation of the traditional RCT is that findings are not always readily disseminated into real world settings [34,35], and their effectiveness across populations and patient characteristics is unknown. Findings from Mi-CARE may provide a model for increasing screening rates in FQHCs serving diverse populations across the country. Given the flexibility of the patient navigation procedures, adoption of these methods may be able to occur more readily, increasing the public health impact.

6. Comment

In response to the significant CRC burden and persistent underutilization of screening, the National Colorectal Cancer Roundtable's (NCCRT) initiative 80% by 2018 sets an important goal for CRC screening. The primary goal of this initiative is to attain a population CRC screening rate of 80% in adults ages 50 and older by the year 2018. In a recently published health policy statement, the Society of Behavioral Medicine (SBM) supported the 80% by 2018 initiative and made recommendations for health care providers who wish to join the initiative [36]. Specifically, SBM recommended that primary care, hospital care, and informal care providers consider the following: 1) Use electronic health records to optimize frequency and type of CRC screening recommendations and track efficiency and use of resources; 2) Engage patients in the planning of CRC screening resources for themselves and your patient population; 3) Offer patient population-based, decision support and navigation services to help patients understand and manage the complex nature of CRC screening planning, preparation, and follow up; 4) Increase public awareness of CRC screening guidelines and community resources for care; and 5) Promote system wide uptake of evidence based screening modalities based on patient engagement through one-on-one provider and patient education. Mi-CARE will use all of these approaches to increase screening uptake to reduce CRC mortality among underserved patients. The results of the trial will be used to determine which navigation methods are more effective overall by patient population and site. Findings will inform further disseminated Mi-CARE across other FQHCs serving low-income and minority patients in the Chicago land area.

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Fig. 1.
Lay patient navigation flow chart.

Fig. 2.
Provider navigation flow chart.