

Research Article

Reducing Colorectal Cancer Incidence and Disparities: Performance and Outcomes of a Screening Colonoscopy Program in South Carolina

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This study evaluated the efficiency, effectiveness, and racial disparities reduction potential of Screening Colonoscopies for People Everywhere in South Carolina (SCOPE SC), a state-funded program for indigent persons aged 50–64 years (45–64 years for African American (AA)) with a medical home in community health centers. Patients were referred to existing referral network providers, and the centers were compensated for patient navigation. Data on procedures and patient demographics were analyzed. Of 782 individuals recruited (71.2% AA), 85% (665) completed the procedure (71.1% AA). The adenoma detection rate was 27.8% (males 34.6% and females 25.1%), advanced neoplasm rate 7.7% (including 3 cancers), cecum intubation rate 98.9%, inadequate bowel preparation rate 7.9%, and adverse event rate 0.9%. All indicators met the national quality benchmarks. The adenoma rate of 26.0% among AAs aged 45–49 years was similar to that of older Whites and AAs. We found that patient navigation and a medical home setting resulted in a successful and high-quality screening program. The observed high adenoma rate among younger AAs calls for more research with larger cohorts to evaluate the appropriateness of the current screening guidelines for AAs, given that they suffer 47% higher colorectal cancer mortality than Whites.

1. Introduction

There is wide variation across population subgroups in cancer incidence, mortality, or both. Nationally in the United States of America, African Americans (AAs) have ≈17% higher colorectal cancer (CRC) incidence and ≈47% higher mortality than Whites [1]. AAs also are diagnosed at younger ages, on average and with later-stage disease, have a higher incidence before the recommended screening age of 50 years, and tend to have worse prognoses even after accounting for

other factors [2, 3]. These disparities tend to be much larger in South Carolina (SC) than in the US average [4, 5].

The majority of CRCs in average-risk individuals arise from the polyp-to-cancer pathway, which translates into an opportunity to prevent cancers by removing polyps detected through screening age-appropriate adults. Of all cancer screening tests, colonoscopy is the most effective both for early detection and, more importantly, for primary prevention of CRC because it enables removal of precancerous polyps before they turn cancerous. Colonoscopy has some

disadvantages, however. It requires specially trained physicians and is expensive and invasive, requiring a well-equipped and well-staffed facility for safe, high-quality performance. Consequently, health insurance remains a key determinant of colonoscopy screening completion, which currently stands at 19.1% among working-age uninsured adults in the 2010 National Health Interview Survey Data, compared to 56.7% among those privately insured [6]. Despite many uninsured individuals having primary care access through the ambulatory care safety net, mainly federally qualified health centers (FQHC), the colonoscopy rate among this subgroup is low, about 24% [7], because FQHCs cannot obtain adequate volumes of charity colonoscopy care.

SC has the 16th highest percentage of uninsured adults in the USA [8] and has a higher proportion of AA population (30%) than the national average. The program, Screening Colonoscopies for People Everywhere in South Carolina (SCOPE SC), was designed to leverage the medical home relationship of FQHCs with uninsured individuals. A sum of \$1 million was authorized by the South Carolina Legislature for the Department of Health and Environmental Control (SCDHEC) to cover screening colonoscopy of average-risk established FQHC patients ≥ 50 years old (≥ 45 years for AAs) with income $\leq 200\%$ of poverty and without private or Medicaid insurance. Based on studies showing that patient navigation improves colonoscopy completion rates [9, 10], the program asked participating FQHCs to use their existing colonoscopy referral channels and funded patient navigation services to maximize screening completion and other facilitation services. The SCDHEC program office organized referrals and follow-up care for individuals who experienced a complication or were diagnosed with cancer.

About 800 screening procedures were targeted, based on an average cost of \$1,000 each (covering provider reimbursement at Medicare rates, patient navigation, and program evaluation). Provider reimbursements were contingent upon reporting to the program, thus allowing for monitoring of procedure quality and completeness. At the end of year 1, SCDHEC assigned the program performance evaluation to an external academic research team, the results of which are presented in this paper.

2. Methods

Four FQHC sites participated in the SCOPE SC program, having been identified based on elevated CRC incidence, mortality, and late-stage CRC rates; resources and infrastructure; and a geographic distribution pattern providing for statewide representation. The program was promoted via direct notification of FQHC staff and outreach workers through promotional materials (postcards and posters) and by including the program on the American Cancer Society's toll-free telephone hotline. Eligible individuals included current FQHC patients with current SC residency, US citizenship (established with the social security number), no health insurance, income $\leq 200\%$ of the federal poverty limit, age eligible (50–64 years for Whites without a CRC family history, 45–49 years for Whites with CRC family history, and 45–64

years for AAs regardless of family history), no gastrointestinal symptoms, and not being up to date with CRC screening per published guidelines (Figure 1). All beneficiaries were referred to by their primary care physician at a participating FQHC. If not a current FQHC patient, they were required to enroll as patients for purposes of adequate care and referral for complications, cancer diagnosis and/or follow-up surveillance.

Each FQHC had at least one navigator dedicated to the program. Eligible patients were identified by the primary physician and referred to the navigator for obtaining preauthorization from SCDHEC program staff. The patient then received a bowel preparation kit that included written instructions, and the procedure was scheduled. Navigators included FQHC nurses or administrative staff who routinely interacted with patients. FQHCs were compensated for navigation, \$25 for the initial referral and associated paperwork and \$75 for successful completion of the procedure. SCOPE SC program staff provided one-on-one training to navigators and FQHC staff administering the program. The training consisted of several hours of instruction emphasizing the importance of an adequate bowel preparation including detailed instructions for patients, methods to help patients plan for their procedure (e.g., obtaining transportation and other care-related advice), and details on program administration, referrals, and other resources.

As a condition of reimbursement, participating FQHCs, endoscopy clinics, FQHCs, and laboratory service providers submitted standard forms on all eligible individuals referred for colonoscopy. Data collected included demographic, relevant family and personal medical history (submitted by FQHCs), clinical procedure and polyp information (by colonoscopy providers), and polyp histopathology features (by laboratory service providers). SCDHEC established a medical quality assurance committee consisting of community-based, SCDHEC, and academic physicians that monitored procedure quality throughout the year by periodically reviewing the clinical and pathology data for all cases submitted by providers. When suboptimal outcomes were identified (low polyp detection rate, poor bowel preparation rate, or placing multiple polyps from different colorectal segments in a single jar), potential causes were discussed by the committee and feedback communicated to providers through the SCOPE SC program manager.

The study sample consisted of year 1 data on all screening colonoscopies provided during fiscal year 2009-10 (July 1 through June 30). The study team systematically reviewed the data files compiled from the patient referral, screening, and laboratory forms together against the original patient forms for accuracy and entered missing/discrepant data. Data entry was completed onsite within the SCDHEC data system. Files were linked, deidentified, and extracted in Excel format into University of South Carolina (USC) computers. The study was approved by the USC and SCDHEC Institutional Review Boards.

Univariate statistics (and chi-square tests where applicable) are used to present the program's efficiency (in outreach and procedure completion), beneficiary demographics, disparity populations reached, procedure effectiveness (cecum

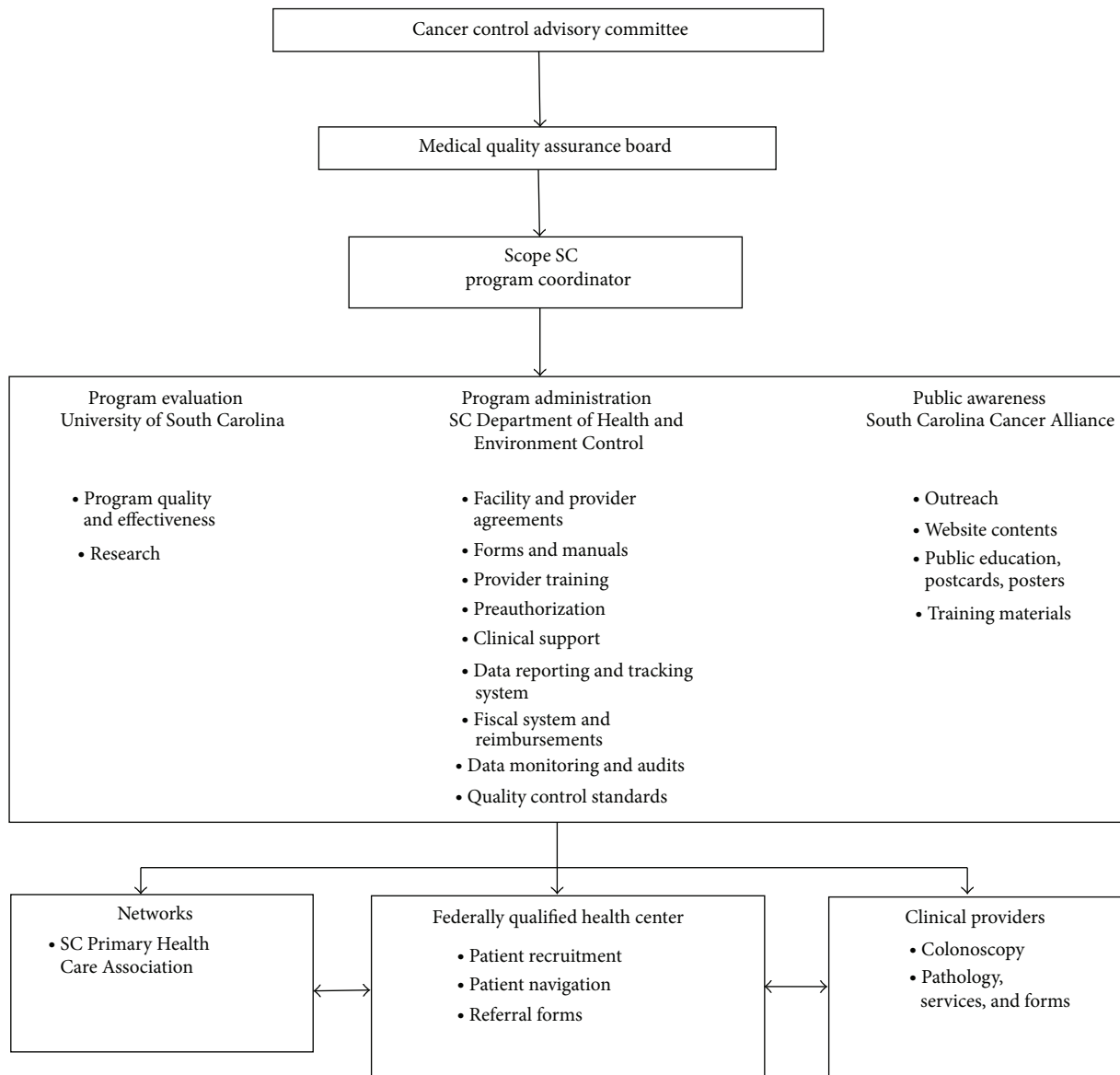


FIGURE 1: SCOPE SC program organization chart.

intubation, polyp detection and retrieval, adenoma, advanced neoplasm, and cancer detection rates), bowel preparation quality, and patient safety (adverse event rate). SAS version 9.2 was used.

3. Results

Table 1 summarizes the SCOPE SC year 1 program performance on efficiency, effectiveness, and patient safety. Of 782 eligible beneficiaries identified by the four participating FQHCs, 665 (85%) completed the procedure. The unadjusted cecum intubation rate was 98.1% (the US Multisociety Task Force (USMSTF), adjusted cecal intubation rate was 98.6%, excluding unintubated cases due to poor bowel preparation) [11], and the circumstance-adjusted cecum intubation rate was 98.9% (excluding unintubated cases due to poor bowel

preparation and medical reasons requiring procedure termination) [12]. All rates, including the unadjusted rate, exceeded the USMSTF benchmark of 95% [11].

The polyp detection rate was 56.4% (proportion of screened persons with ≥ 1 polyp detected). The adenoma detection rate (having any polyp with an adenomatous or carcinomatous histology, excluding hyperplastic polyps and normoplastic or lymphoid tissue) was 27.8% overall, 34.6% for men and 25.1% for women. Both rates exceed the USMSTF minimum standards of >25% for men and >15% for women [11]. The advanced neoplasm detection rate (adenomas ≥ 10 mm, villous/tubulovillous adenomas, high-grade dysplasia, or cancer) was 7.7% overall, 9.9% in men and 6.8% among women. Three cancer cases were found, 0.4% of those were screened. No benchmark exists for advanced neoplasm detection [11], although the USMSTF notes a documented

TABLE 1: SCOPE SC program performance in year 1: efficiency of patient recruitment, effectiveness of procedure performance, and patient safety.

Performance indicator	Number/%
Program efficiency	
Program target number of colonoscopy screenings (funding available)	800
Number of eligible beneficiaries identified	782
Number of who completed colonoscopy	665
% of eligible beneficiaries navigated through procedure completion	85%
Number of performing physicians	32
Bowel preparation status documented (benchmark 100%) [12]	98.5%
Patient safety: adverse event rate (benchmark 2%, all event types) [12]	0.9%*
Procedure performance quality	
Cecal intubation rate (benchmark 95%) [12]	98.9%
Bowel preparation status rated fair, good, or excellent	92.1%
Proportion of screened persons with polyp(s)	56.4%
Proportion of polyps completely removed	93.1%**
Proportion of polyps retrieved for pathology exam (benchmark 95%) [11]	99.9%
Polyp, adenoma, and cancer detection	
Proportion of screened persons with polyp(s)	56.4%**
Proportion of screened persons with hyperplastic polyp(s)	34.6%**
Proportion of screened persons with adenoma(s) found (ADR) (benchmark 15% for women and 25% for men) [12]	27.8%
Proportion with advanced neoplasm removed (cancer and polyps at imminent risk of cancer)	7.7%**
Diagnosed with colorectal cancer	3 (0.45%)
Total number of polyps removed	917
Total number of adenomas removed	338
Total number of advanced neoplasms removed	58

Advanced neoplasms include adenomas ≥ 10 mm in diameter, adenomas with villous or tubule villous features or high-grade dysplasia, and cancer or carcinoid tumor.

* $n = 6$ (1) bleeding, (2) incomplete colonoscopy due to torsion, and (3) unspecified but having good bowel preparation and the procedure was completed, no perforations.

** No national quality benchmarks exist for these indicators.

range of 3–10% [11] in US colonoscopy cohorts. The SCOPE SC rate is close to the upper end of the documented range.

Adverse events were documented in 0.9% of procedures, within the benchmark limit ($n = 6$ cases, (1) bleeding, (2) incomplete colonoscopy due to torsion, and (3) unspecified but having good bowel preparation and the procedure was completed, no perforations). The USMSTF benchmarks are $<1/300$ case of sedation-related complications requiring endotracheal intubation or mask ventilation, <1 bowel perforation per 1000 procedures, and $<1/100$ major postpolypectomy bleeding [11]. Documentation of bowel preparation status was available for 98.5% of recipients (655 out of 665), slightly lower than the benchmark of 100% [11]. Bowel preparation status is important for maximizing polyp detection [13, 14], and poor bowel preparation may trigger cancellation of the procedure. Therefore adequate bowel contributes to the cancer protection effectiveness of colonoscopy [15]. Bowel preparation status was good or excellent in 69.3%, fair in 22.7%, and poor in 7.9% of the patients. The nationwide rate of poor preparation is 25% [14]. There are no USMSTF benchmarks for rates of good/poor bowel preparation although a benchmark exists for the rate of documentation of bowel preparation status (100%).

Of a total of 917 polyps found, 916 (99.9%) were retrieved for pathological examination (benchmark 95%) [11]. A total of 338 adenomas (including advanced neoplasms) were removed among the 665 patients, for an average of 0.51 adenomas per subject screened. Of these, 58 (0.09 per subject screened) were advanced neoplasms. There are no benchmarks established for the mean number of adenomas per screened subject. Three cancer cases were found at colonoscopy, two cancers located in the rectum and one in the sigmoid colon. Of 55 advanced adenomas, 76.4% were 10 mm or more in diameter, 16.4% had villous or tubulovillous features, and 5.5% showed high grade dysplasia. Additionally, there were 8 serrated adenomas. Among the 45–49-year-old AAs, 6 had advanced adenomas.

Table 2 shows the demographic characteristics of beneficiaries, the adenoma rate, and advanced neoplasm rate among the demographic subgroups. Most beneficiaries were female (71.1%), African American (71.1%), and lived in the Midlands region of SC (75.3%). The mean age was 55.2 (SD = 4.9) years, and majority (64.4%) were aged 50–59 years. The adenoma detection rate among males was 34.6%, and among females 25.1% ($P = 0.01$). The rate was 26.0% among those 45–49 years old (all AA), 28.4% in the 50–59 year age

TABLE 2: SCOPE SC beneficiary demographics and corresponding adenoma detection rates ($n = 665$).

	Number of beneficiaries	Adenoma detection rate	Advanced neoplasm detection rate
Geographic region			
Upstate	142 (21.5%)	38/141 (27.0%)	16/141 (11.3%)
Midlands	501 (75.3%)	140/498 (28.1%)	33/498 (6.6%)
Low country	22 (3.3%)	6/22 (27.3%)	2/22 (9.1%)
Patients			
Gender			
Male	192 (28.9%)	66/191 (34.6%)	19/191 (9.9%)
Female	473 (71.1%)	118/470 (25.1%)	32/470 (6.8%)
Race*			
White	164 (24.9%)	51/163 (31.3%)	17/163 (10.4%)
Black	468 (71.1%)	123/465 (26.5%)	31/465 (6.7%)
Other	26 (4.0%)	5/26 (19.2%)	2/26 (7.7%)
Age (years)**			
45–49***	77 (11.6%)	20/77 (26%)	6/77 (7.8%)
50–59	426 (64.4%)	120/423 (28.4%)	35/423 (8.3%)
60–64	159 (24.0%)	43/158 (27.2%)	9/158 (5.7%)
Family history			
Yes	85 (12.8%)	25/85 (29.4%)	9/85 (10.6%)
No or missing****	580 (87.2%)	159/576 (27.6%)	42/576 (7.3%)

Note: denominators for adenoma and advanced neoplasm detection rate vary due to missing data.

*Race information was missing for 7 patients.

**Age information was missing for 1 patient.

***Includes 14 Whites screened due to a family history of colorectal cancer.

****Question design did not permit distinction between absence of family history and nonresponse.

group, and 27.2% in the 60–64 age group ($P = 0.89$). When examined by race, 31.3% of Whites, 26.5% of AAs, and 19.2% of other race/ethnicities had ≥ 1 adenoma ($P = 0.31$). There was no significant difference in adenoma rates by geographic region. AAs aged 45–49 years were as likely as older Whites and AAs (aged over 50 years) to have an adenoma after controlling for gender ($P = 0.56$).

Table 3 presents the performance of SCOPE SC in addressing racial disparities in CRC. Of screening-eligible beneficiaries recruited at the FQHCs, 71.2% were AA. Among those who completed colonoscopies, 71.1% were AA. The adenoma detection and advanced neoplasm detection rates are also presented.

4. Discussion

There is little documentation of state-funded CRC screening programs for the indigent, particularly statewide programs emphasizing colonoscopy as the primary screening test. One study documented the program design and beneficiary profile of Louisiana's state-funded screening program that offered fecal immunochemical testing (FIT) to the medically indigent attending FQHCs followed by colonoscopy for those with abnormal FIT tests [16]. The State of Delaware has implemented a colonoscopy-based screening program for the uninsured since 2002. Its performance and outcomes up to

2009 are documented [17]. By 2009 the program had wiped out racial disparities in screening (74% of AAs and Whites being up to date with CRC screening in the BRFSS 2009 data, of which 85% was accounted for by colonoscopy screening in both racial groups). Similar to the Delaware program the SCOPE SC program chose to fund primary colonoscopy screening in view of low (per test) sensitivity of FIT for CRC prevention [18]. In the SC program 85% of 782 persons who were recruited completed the screening colonoscopy procedure compared to 66% of 975 persons recruited for the FIT procedure in Louisiana, despite the significantly invasive and therefore potentially intimidating nature of colonoscopy relative to FIT.

The design and performance of the SCOPE SC program in year 1 were consistent with the US Healthy People 2020 goal of “health equity, elimination of disparities and improving the health of all groups” by “facilitating high-quality, longer lives, free of preventable disease, disability, injury and premature death” [19]. The Healthy People 2010 goal of reducing CRC mortality to 13.9/100,000 [19] remained far beyond reach (current rate 21.9/100,000) [1], partly due to disproportionately high CRC mortality among AAs [20] (47% higher than among Whites). In the SCOPE SC program 71% of beneficiaries were AA, and the mean beneficiary age was 55.2 years. All of these features are encouraging. Considering the potential for cumulative cancer mortality gain, the mean

TABLE 3: SCOPE SC performance in addressing racial disparities in colorectal cancer.

Race/ethnicity	Eligible beneficiaries recruited	Percent completed colonoscopy	Percent with adenomas found	Percent with advanced neoplasms
African American	493	468 (95.0%)	123 (26.3%)	31 (6.6%)
White	172	164 (95.3%)	51 (31.1%)	17 (10.4%)
Other/missing	117	33 (28.2%)	10 (30.3%)	3 (9.1%)
Total	782	665 (85.0%)	184 (27.7%)	51 (7.7%)

beneficiary age was close to the recommended screening commencement age of 50 years, indicating that SCOPE SC gave the beneficiary cohort an early start for optimal preventive benefit, with more potential life years saved than would be the case if the mean age were higher. A high proportion of AA among beneficiaries served (71% compared to the state's overall AA population of 29%) indicates that SCOPE SC succeeded in focusing more resources on this high-disparity group. Equal proportions of screening-eligible AAs and Whites recruited actually completed the procedure. Of the AA population in SC 51.3% live below 200% of poverty compared to 31.4% of Whites [21]. The screening coverage advantage that was achieved for AAs relative to Whites is consistent with the performance of Delaware's statewide screening program for the medically indigent implemented from 2002 to 2011. The Delaware program achieved a 100% reduction in colonoscopy screening disparities between AAs and Whites [17]. One study limitation is the lack of information on the reasons/barriers for completion of the procedure among those who did not complete the procedure.

Almost 12% of beneficiaries were AAs aged 45–49 years. Unexpectedly, we found that the adenoma rate and advanced neoplasm rate in this age group were similar to the rates found among older Whites and AA. A study limitation is that potential recruitment bias favoring those with a family history among younger AAs cannot be ruled out. Although the patient referral form had a question on family history, the design was such that nonresponse could not be distinguished from those without a family history. However the frequency of adenomas was not different among those with a family history of CRC (Table 2).

Our finding suggests that SCOPE SC's innovation of extending coverage to AAs aged 45–49 years is justified and is consistent with the American College of Gastroenterology recommendations [22], earlier than the American Cancer Society's recommended screening age of 50 years uniformly for all racial groups [23]. Currently almost no insurance plan covers screening prior to 50 years of age. Our findings emphasize the need for further research with larger cohorts to verify the evidence for changing the screening eligibility age for AAs. On another note, the preponderance of women (71%) among SCOPE SC beneficiaries indicates that more focused efforts to recruit males are needed.

Provider engagement and influence on patients' decisions to undergo elaborate colon preparation are facilitated by an established doctor-patient relationship, usually not an option for uninsured patients relying on episodic charity care received from sporadically available providers in emergency

rooms and free clinics. Because FQHCs serve as a primary care medical home for the uninsured, they present an opportune setting for colonoscopy screening programs targeting the medically indigent. The SCOPE SC program chose to deploy FQHCs as the patient recruiting sites and provided funds to cover colonoscopy costs and patient navigation, which yielded highly encouraging results: rapid accrual of targeted beneficiaries, very high procedure completion rate of 85.0%, and high rates of acceptable bowel preparation. The critical role of patient navigation in improving bowel preparation and adenoma detection is well documented [24–26]. The procedure completion rate of 85% exceeds the documented rate of 66% following structured patient navigation efforts in New York City [9] and is similar to a recently documented rate of 91% colonoscopy completion following a comprehensive patient navigator program in New York City [27].

Despite meeting or exceeding the USMSTF benchmark rates for cecum intubation, polyp retrieval, and adenoma detection, the cohort had a suboptimal bowel preparation rate (considering fair and poor preparation) of 30.6%, which is consistent with the 34% rate achieved in a Medicaid primary care clientele in New York City by implementing comprehensive patient navigation services [27]. The cohort's 7.9% rate of poor bowel preparation (which causes cancellation of the procedure and sometimes termed as "inadequate preparation" [27]) is much lower than the national average of 25% [14]. The higher rate of adequate bowel preparation for the cohort is attributable, at least in part, to the detailed data collection system coupled with ongoing quality monitoring and feedback by an expert panel, instead of the widely prevalent practice of after-the-fact program evaluation typical of most programs. Three cancer cases were detected and referred for treatment. All were asymptomatic patients. Cancer stage information is not available.

In conclusion, year 1 of the SCOPE SC program served as a successful pilot validation of the program's innovative design elements: leveraging the medical home relationships of the uninsured with FQHCs, purposive funding of patient navigation, and extending coverage to AA aged 45–49 years. Results show that high completion rates can be achieved within an *ad hoc* program's fiscal year timeline. The program design enabled scarce dollars to selectively reach out to populations with the greatest need, thereby maximizing the program's potential contribution to the healthy people 2020 goal for reducing overall CRC mortality. Expansion of earmarked appropriations for colonoscopy screening of the medically indigent in SC makes sound economic sense as

the state and federal governments stand to reap Medicaid and Medicare cost savings on CRC treatment in later years. Appropriations should be linked to a structured quality management system via establishment of provider accountability systems that track performance against quality indicators.

The relatively high rate of adenomas and advanced neoplasms among AAs aged 45–49 years is both intriguing and potentially very important. Given the increased probability of more aggressive disease at younger ages [28], this has major implications for policy and practice aimed at reducing racial disparities in CRC incidence and mortality. This result calls for further investigation with larger screening cohorts.

Abbreviations

CRC:	Colorectal cancer
FIT:	Fecal immunochemical testing
FQHC:	Federally qualified health centers
SC:	South Carolina
SCDHEC:	South Carolina Department of Health and Environmental Control
SCOPE SC:	Screening Colonoscopies for People Everywhere in South Carolina
US:	United States
USC:	University of South Carolina
USMSTF:	US Multisociety Task Force.

Disclosure

The content is solely the responsibility of the authors and does not necessarily represent the official view of the National Cancer Institute or the National Institutes of Health.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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