

The Role of Patient Navigation on Colorectal Cancer Screening Completion and Education: a Review of the Literature

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Abstract Although the general assumption is that patient navigation helps patients adhere to CRC screening recommendations, concrete evidence for its effectiveness is still currently under investigation. The present literature review was conducted to explore effectiveness of patient navigation and education on colorectal cancer (CRC) screening completion in medically underserved populations. Data collection included PubMed, Google Scholar, and Cochrane reviews searches. Study inclusion criteria included randomized controlled trials and prospective investigations that included an intervention and control group. Case series, brief communications, commentaries, case reports, and uncontrolled studies were excluded. Twenty-seven of the 36 studies screened for relevance were selected for inclusion. Most studies explored the utility of lay and clinic-based patient navigation. Others implemented interventions that included tailored messaging, and culturally and linguistically appropriate outreach and education efforts to meet CRC screening needs of medically underserved individuals. More recent studies have begun to conduct costeffectiveness analyses of patient navigation programs that impacted CRC screening and completion. Peer-reviewed publications consistently indicate a positive impact of patient navigation programs on CRC screening completion, as well have provided preliminary evidence for their cost-effectiveness.

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Department of Family and Community Medicine, Baylor College of Medicine, Houston, TX, USA **Keywords** Colorectal cancer · Patient navigation · Fecal occult blood test · Fecal immunochemical test

Introduction

Burden of Colorectal Cancer

In the USA, colorectal cancer (CRC) is the third most common cancer in both men and women [1]. The overall incidence of CRC in Harris County Texas is 41.8 per 100,000, which is higher compared to the Texas incidence of 40.2 per 100,000 [15]. This is much higher than the goal of 38.6 per 100,000 recommended by the Centers for Disease Control (CDC) and Prevention and the National Institute of Health (NIH) in the Healthy People 2020 objectives [35]. CRC is the second leading cause of cancer-related deaths among male and female residents of Harris County. In 2015, the number of new cases of CRC in Harris County was projected at 1055 (men, 570; women, 485) with 459 deaths [15].

CRC disproportionately affects African Americans; the overall age-adjusted incidence for CRC in African Americans in Harris County is 54.0 per 100,000 (68.2 per 100,000 men and 44.5 per 100,000 women). Furthermore, worse CRC outcomes are observed in African American women, possibly because of more aggressive tumors [33], which result in earlier distant spread, and ultimately death. CRC is the second most common type of new cancer diagnosed in Hispanics (41.8 per 100,000 men and 28.2 per 100,000 women). For Asians, CRC ranks third (42.4 per 100,000 men and 23.5 per 100,000 women). For non-Hispanic whites, CRC also ranks third in new cancers (51.7 per 100,000 men and 34.6 per 100,000 women). The overall mortality rate from CRC in Harris County is 15.6% (based on data from 2008 to 2012) [33]. This is higher than the goal of



14.5% that the CDC and NIH have put forth in the Healthy People 2020 objectives [35]. Other than biological factors, the prevalent view for differences in CRC incidence include delay in diagnosis, lack of insurance, and lack of knowledge and understanding about the benefits of early initiation of CRC screening. Additionally, previous experiences resulting in lack of trust in health care systems, and cultural beliefs about cancer, have been shown to contribute to major gaps in essential CRC screening services [3, 12, 22, 31]. For example, findings from community-based cancer screening interventions indicate a general sense of fatalism among African Americans regarding CRC outcomes [2, 18].

Rationale for the Literature Review

The impact of patient navigation on CRC screening has been evaluated in both community- and hospital-based interventions. The general assumption is that patient navigation is useful in helping patients adhere to CRC screening recommendations; however, concrete evidence for its effectiveness is still currently under investigation. One major limitation in previous studies has been the lack of inclusion of medically underserved patient populations, as well as differences in study design, which makes it difficult to make comparisons between studies. The present literature review was undertaken to explore the effectiveness of patient navigation and education on CRC screening completion in medically underserved populations.

Methods

Overview

We conducted a comprehensive search of the literature for studies that have included patient navigators as key strategy for improving completion and quality of CRC screening. This literature review involved the use of several search engines including PubMed, Google Scholar, and Cochrane reviews. The following terms were used to identify articles: patient navigation, colonoscopy, fecal occult blood test (FOBT), fecal immunochemical test (FIT), CRC screening and outreach, CRC screening and prevention education, racial/ethnic disparities in CRC, and patient-centered approaches to CRC care. In addition, manual searches were conducted of studies referenced in these publications. We included randomized controlled trials and prospective investigations that had an intervention and control group. Case series, brief communications, commentaries, case reports, and uncontrolled studies were excluded. In instances where authors had multiple publications that presented data on the same population, the most recent publication was considered. Literature reviews and studies that presented design of CRC patient education protocols without including findings were excluded from the review as well. The review is subdivided into several major themes: (1) racial/ethnic disparities in CRC screening, (2) CRC prevention and education strategies, (3) impact of patient navigation on CRC screening, (4) tailored CRC education, and (5) cost-effectiveness of patient navigation programs to improve CRC screening completion.

In order to conduct a comprehensive review of the methodology followed in each research study, the Consolidated Standards of Reporting Trials (CONSORT) guidelines was used [34]. The CONSORT checklist was used to review how studies were designed, analyzed, and interpreted. This checklist aided in the decision of which studies to include in the literature review.

Results

Overview

As can be seen in Fig. 1, 79 articles were initially identified. Of these articles, 43 did not mention CRC screening as main study outcome, did not specifically explore effectiveness of patient navigation on CRC screening, were concept papers, or presented policy statements. Another nine articles were excluded from the review because they presented literature reviews of studies conducted within the same time period evaluated in the present review, or were of poor methodological quality. In the end, 27 articles published in peer-reviewed journals between 2003 and 2016, were included in this review. Of these studies, 18 were RCTs [3–6, 8–14, 16, 20, 24, 25, 28–32, 38], five were descriptive or cross-sectional [7, 13, 17, 19, 23], and four were prospective studies [21, 27, 28, 38].

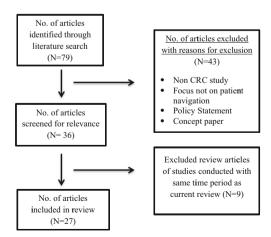


Fig. 1 Study Flow Diagram No. of articles identified through literature search (N = 79)



Table 1: Characteristics of the 27 studies included in the review

Author/year	Setting	Intervention	Design	Goal	Sample size	Results	Conclusion
Raich PC, et al., 2012 [29]	Safety-net health care system in Denver—PN research	Patient nav. to follow-up of abnormal (abn.) CRC screening (scr.)	RCT Racial/eth	Racial/ethnic disparities in colorectal cancer screening Determine impact of PN on $N = 235$ resolution of abn. CRC scr. 72% mino	a screening $N = 235$ 72% minority	Time to resolution of abn. CRC ser. was significantly shorter in the PN group.	Decreasing time to resolution of abn. CRC scr. could lead to earlier detection and improved CA
Hendren S, et al., 2012 [11]	program Patients with newly diagnosed cancer	N	RCT	Measure PN effects on CA-QOL among patients with newly diagnosed cancer. QOL was measured	-PN: $n = 165$ -Control: n = 154 -Total $N = 319$	ere similar between or patient factors, ciated with	outcomes. No statistically sign. effect on CRC specific QOL was observed among nav. patients.
Fiscella K, et al., 2012 [8]	Two sites from the PN (trained lay national PN navigators) v research care program	PN (trained lay navigators) vs usual care	RCT	with FAC 1-C. Assess impact of PN on outcomes for patients diagnosed with CRC.	N = 438 44% racial/- ethnic minorities -46% low education 18% uninsured 9% non-Engl.	Improved COL. No significant group differences observed in time to completion of CA Tx, satisfaction with CA-related care, or psychological distress. In sub-group analysis, higher satisfaction with CA care observed among uninsured, low Engl. proficiency, and non-Engl. primary lang.	Sub-group analysis suggests improved satisfaction with CA care among disadvantaged individuals who underwent PN.
Wells KJ, et al., 2012 [36]	Medically underserved populations	Lay PN	Cluster randomized trial	Determine whether a lay PN program reduced time between abn. CRC scr. and definitive dx.	language -Nav.: $n = 588$ -Control: $n = 679$ -Total	no n time to for , insurance	Time to CRC diagnosis was not impacted by PN.
Jandorf L, et al., 2013 [16]	Mount Sinai primary clinic	-Peer-patient navPro-patient navigation (salaried staff) vs - standard nav.	RCT	Determine whether different patient navigation formats increased CRC scr. among AAs.	N = 126/ -Peer-PN: n = 181 -Pro-PN: n = 123 Standard	oups. Il groups	Any type of patient navigation service is likely to be beneficial to help AAs complete CRC scr.
Honeycutt S, et al., 2013 [13]	Rı	4 intervention clinics received PN vs. 9 comparison clinics	Quasi-experimental	Evaluate effectiveness of PN addressing individual and systemic barriers to CRC	FIN: m = 40 $N = 809$	e	PNs can increase preventive health scr. among the low-income in a rural set-
Myers RE, et al., 2014 [24]	neaun centers Primary care practices in Philadelphia	-Tailored PN intervention—mailed FOBT, telephone nav. and reminder -Standard Intervention	RCT	Set. Determine effect of preference-based tailored nav. (TNI) on CRC set. adherence and related outcomes among AAs.	TNI: $n = 384$ SI: $n = 380$ Total N: 764	Versus 7%, OR = 7.5, $p < 0.01$. CRC ser, adherence in the TNI group was statistically sign higher than the SI group after 6-month follow-up (OR 2.1, 95% CI = 1.5–2.9).	Img. TNI intervention may be an effective intervention to increase CRC scr. among AAs.
Percac-Lima S, et al., 2014 [28]	Community Health Center	(51)—usual care. Culturally CRC scr. PN program	Prospective RCT	Evaluate impact of PN on equity of CRC prevention over a 5-year period.	Intervention: $n = 3115$ Control: $n = 43,905$ Intervention:	CRC scr. incr. over 5 years, among Latino and non-Engl. speakers at the CHC $(p < 0.001)$.	PN program increased CRC scr. among the vulnerable.



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Author/year	Setting	Intervention	Design		Goal	Sample size	Results	Conclusion
Home HN, et al., 2015 [14]	Baltimore, MD— the Cancer Prevention and Treatment Demonstration Project	PN-led intervention that assisted participants with overcoming scr. barriers			Investigate the effect of patient nav. on increasing CRC scr. adherence among older AAs.	n = 578 Control: $n = 642$	PN group sig more likely to be up to date with CRC scr. (OR 1.55, 95% CI, 1.07–2.23) -Colonoscopies benefitted from nav.(OR 1.53, 95% CI, 1.07–2.19), but not FORT	PN intervention increased CRC scr. among older AA adults.
Braun KL, et al., 2015 [5]	Molokai' General Hospital in Hawaii	Lay navigator case managers assessed CA scr. services	RCT		Increase CA scr. of Asian and Pacific Islanders Medicare beneficiaries	N = 488	Intervention group exhibited higher scr. prevalence compared to controls $(20.7 \text{ vs}.12.6\%, p = 0.02,$	Nav. services can increase cancer scr. in Medicare patients with disparities.
Wells KJ, et al., 2016 [37]	Eight PN research program sites	PN helped assess resources and address barriers to CRC scr.	RCT		Explore effect of nav. on satisfaction with CRC care.	N = 1788	respectively) sign differences observed in satisfaction with CRC care between intervention and control groups ($p > 0.05$)More Hispanic and AAs indicated lack of satisfaction with CA care than whites.	No differences in patient satisfaction with cancer care between PN- and control group.
Goldman SN, et al., 2015 [9]	Community Health Centers	PN outreach vs, usual care.	RCT	Colorectal	Colorectal cancer prevention and education strategies Determine whether FOBT $N = 420$ increased as result of outreach.	strategies $N = 420$	-Intervention patients sign more likely to complete FOBT compared to usual care (36.6 vs. 14.8%, <i>p</i> < 0.001, respectively)Participants who visited the clinic often more likely to complete CRC	Medically underserved populations could benefit from having cost-benefit analyses to increase CRC scr.
Singal AG, et al., 2016 [32]	Safety-net health system	PN-led outreach invitations vs. usual care	RCT		Explore effectiveness of mailed CRC outreach for increasing FIT and colonoscopies.	-FIT: n = 2400 -Colonoscopy: n = 2400 -Usual care: n = 1199	Sci. CRC scr. increased sig among mailed outreach. FIT-based outreach was found to be more effective than colonoscopy based outreach.	CRC outreach should include longer follow-up ensure complete CRC scr.
Braschi, CD, et al., 2014 [3]	Braschi, CD, Latino population et al., 2014 [3]	Culturally targeted patient navigation vs standard patient navigation.	In RCT	npact of pat	Impact of patient navigation on colorectal cancer screening Explore effect of a culturally	cer screening Culturally targeted PN group: n = 2.25 Standard PN group: , - 1.67	No sign differences observed in colonoscopy scr. rates between the study groups. Language acculturation and annual income above \$10,000 were associated with colonoscopy completion.	Highly acculturated Hispanic population can benefit from extensive barrier resolution services.
Green, B. B, et al., 2014 [10]	Western Washington State—21 primary care medical centers	Nurse-led patient nav. vs. usual care	RCT		Determine whether a nurse-led patient nav. education intervention led to timely colonoscopy completion after a positive FOBT test or abn. sigmoidoscopy.	N = 147	The majority of patients (85.7%) completed a colonoscopy after 6 months, but results were not statistically sig. No sig differences in time interval between positive screening test and	Larger studies with longer follow-up periods are needed to determine whether patient nav. improves completion of colonoscopies.
Meade, C. D, et al.,	9	hospital-affiliated	Lay PN program vs. usual care	ram vs.	Descriptive	Report lessons leamed	Iollow-up between study groups. Report lessons $N = 588$ Hispanic patients learned	-The lay PN program effective in helping



Author/year	Setting	Intervention	Design	Goal	Sample size	Results	Conclusion
2014 [24]		outpatient clinics in West Central Florida			from implementing lay PN program to improve CRC scr. among primary care medically underserved patients.		patients through a complex health care systemCombination of lay and professional patient nav. enhances coordination of CRC care.
Utility of different types of patient nav. (lay and professional) services for improving CA disparities should be further evaluated.							
Pelto, D J, et al., 2015 [27]	Mount Sinai primary care clinic	PN vs. usual care patient navigation: culturally and linguistically appropriate health education.	Secondary analysis from two prospective PN cohorts	Determine whether a patient naw, program targeted at AA and Latino participants helped increase CRC awareness and subsequently led to colonoscopy	AA and Latino patients $N = 742$	Patients in the nav. arm sign more likely to complete colonoscopy compared to the non-nav. arm. Language of health education instruction provided by PNs and patient income were sig predictors of colonoscopy completion	Intrapersonal (fear/anxiety) and interpersonal (poor provider-patient communication, PN issues) should be considered in education and counseling of A A A
Ritvo PG, et al., 2015 [30]	21 primary care practices in Ontario, Canada	Tailored nurse navigation intervention (TNI)—CRC scr. education, review of stool tests, and sex mediamore	RCT	Increase CRC scr. completion.	Primary care patients $50-74$ $N = 5240$	RC scr. rol	Patient navigation that included colonoscopy referral or stool test kit provision sign. increased CBC or completion
Liu G, et al., 2015 [21]	University-based family medicine residency	Lay CRC scr. navigator to increase colonoscopy or fecal immunochemical test (FIT).	Prospective	Determine utility of lay patient N = 1394 navigation on completion of CRC ser.	<i>N</i> = 1394	with patients who were vith CRC scr., navigated wed a sign, increase of screening completion 12 months.	This study providents. This study provided evidence for the utility of a lay cancer navigator for increase CRC scr. rate.
Myers RE, et al.,	Primary care	Tailored navigation (TNI), standard nav.	RCT	Tailored colorectal cancer education Assess impact of a tailored Nav. intervention vs	on $N = 945$ TNI: $n = 312$	CRC ser. higher for intervention groups compared to controls (TNI:	TNI and SI sig positive effects on colonoscopy



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Author/year	Setting	Intervention	Design	Goal	Sample size	Results	Conclusion
2013 [24]		(SI), vs usual care control group		standard mailed intervention on CRC scr. adherence.	SI: $n = 316$ Control: $n = 317$	385, SI: 33%, vs. control: 12%). No differences observed in scr. completion between TNI and SI.	completion compared to usual care.
Green BB, et al., 2013 [10]	21 primary care medical centers	Nurse nav. ("navigated") compared to EHR- linked mailings ("automated"), and automated plus tele- phone assistance ("assisted")	4-group parallel-design RCT	Determine whether use of EHRs, automated mailings, and stepped increases improve CRC scr. over 2 years.	N = 4675	to tre, CI	-EHR-linked, and mailed CRC scr. had twice as many current scr. over 2 yearsAssisted and nav. groups had smaller stepped increases.
Lairson DR, et al, 2014 [20]	Primary care patients	lored nav. erived call er mailed / and uctions;	RCT	Determine cost-effectiveness of an SI and TNIs to increase CRC scr.	Control group: n = 317 SI group: n = 316 TNI group: n = 312	ant er	TNI more effective than SI, but cost higher per additional patient.
Daskalakis C, et al., 2014 [6]	Primary care patients	type of CRC patient ncc, and red patient nav.	RCT	Assess effects of scr. preference and telephone nav. for CRC scr. completion.	N = 945	-Preference not associated with overall -Preference influences type scr. -Mailed access to FIT and colonoscopy -Access and navigation to associated with almost three-fold FIT and colonoscopy increase in colonoscopy scr. (OR = 2.6 , $p = 0.001$) and the final profession and the patient nav. associated with increased overall scr. (OR = 2.1 , $p = 0.005$).	-Preference influences type of CRC scr. tests -Access and navigation to FIT and colonoscopy more effective than tailoring scr. to preference.
Donaldson EA, et al., 2012 [7]	Three community hospitals in the USA	PN from abn. CR. diagnostic reso	ctiveness of patient navig Cross-sectional	Cost-effectiveness of patient navigation programs to improve colorectal cancer screening completion C ser. to C coss-sectional Assess incremental C ser. C cost-effectiveness of adding C cost-effectiveness of adding C nostic resolution C to standard care. C cost-effectivene C cost-eff	rectal cancer scre $N = 411$	I patients with abn. g to get timely diagnon. on. ss ratio \$1192 to C diagnostic	Implementation of PN services may be a cost-effective strategy in addition to standard CA care.
Jandorf, L, et al., 2013 [17]	Urban minority population	Professional health education group vs community-based	Descriptive	Conduct cost-effectiveness analysis of a patient nav. program to increase colonogonies	N = 503	esulted in 78.5% by completion. resulted in a profit for the resulted in a	Patient nav. can generate revenue due to increased CRC screening
Ladabaum U, et al., 2014 [19]	New York City	Cost-effectiveness of patient nav. for colonoscopy screening	Descriptive/prospective	De	CRC no scr. group: $n = 551$ CRC	Ys and 800 per o nav.	Colonoscopy nav. cost-effective and 1-time nav. may be cost-saving
			Prospective		colonosco- py group: n = 453 CRC nav. group: n = 392 N = 370		



A PN-led CRC scr. interven life in cost-effective man-ner. creased likelihood of scr and improved quality of tion substantially in-Conclusion The CCMN program resulted in net health care savings of \$1148 per participant Results Hispanic men Sample size 50 years old constructed to determine cost-effectiveness of the CCMN program Markov model was CRC male navigation (CCMN) program Intervention University Health in San Antonio, Setting Fable 1: (continued) 2015 [38] Author/year Wilson FA,

assessment of cancer therapy, Engl English, abn abnormal, scr screening, AA African Americans, Marstat marital status, FOBT fecal occult blood test, FIT fecal immunochemical test, EHR electronic health record, sig significant, Dx diagnosis, QALY quality ddjusted life years nav navigation, PN patient navigator, CRC colorectal cancer, CA cancer, QOL quality of life, FACT-C functional

Review of Studies Included in the Literature Review

Characteristics of the studies are outlined in Table 1. The main topics in the majority of publications were interventions that explored ways to change CRC screening behaviors in medically underserved populations. Some explored the utility of traditional provider-patient interactions as motivation to obtain CRC screening [9, 10, 14, 28]. Other studies implemented interventions that included tailored messaging [6, 10, 18, 21, 25, 32], lay and clinic-based patient navigation programs [5, 8, 11, 13, 14, 17, 26, 29, 30, 37, 38], and culturally and linguistically appropriate outreach and education efforts to meet the CRC screening needs of medically underserved individuals [3, 9, 16, 18, 26]. A total of four studies conducted cost-effectiveness analyses of their patient navigation program to improve CRC screening [7, 17, 20, 38].

With the exception of studies conducted by Braschi CD. et al., Fiscella K, et al., Green BB, et al., Jandorf L, et al., Hendren S, et al., and Wells KJ, et al. in 2012 and 2016 [3, 8, 10, 17, 11, 37, 38], the majority of studies that had a patient navigation component demonstrated a positive impact on timely CRC screening [6, 9, 10, 13, 14, 26, 28–30, 33]. The patient navigation component in these studies included a number of barrier resolution services including help with transportation, health insurance, traditional patient reminder systems, and attention was given to implementing culturally and linguistically appropriate CRC education. For example, Pelto DJ, et al. [27], in a secondary analysis using data from two prospective PN cohorts, determined whether a patient navigation program targeted at African American and Latino participants helped increase CRC awareness and subsequently led to colonoscopy completion. In this study, a total of 742 African American and Latino patients were randomized to either a patient navigation or non-navigation arm. Patient navigation consisted of a health education intervention delivered in a culturally and linguistically appropriate manner. Patients in the navigation arm were significantly more likely to complete a colonoscopy compared to the non-navigation arm. In addition, language of health education instruction provided by patient navigators and patient income were significant predictors of colonoscopy completion. Similarly, Braschi CD et al. [3] explored the effect of a culturally appropriate patient navigation program targeted at a Latino patient population. Study groups consisted of patients randomized to a patient navigation group including tailored CRC education and a standard PN group (non-tailored). Key independent variables were socio-demographic and personal information. Main results revealed no significant differences in colonoscopy screening rates between the study groups. However, language acculturation and annual income above \$10,000 were significantly associated with colonoscopy completion.



Green BB and colleagues [10] in a 4-group parallel-design RCT, examined whether the use of nurse navigation, EHR-linked mailings (automated), and combined automated with telephone assistance improved CRC screening over 2 years. Results showed that in comparison with usual care, EHR-linked mailings, and nurse navigation led to twice as many patients being current with CRC screening (usual care, 26.3%; EHR-linked, 50.8%; navigated, 64.7%).

In another study that explored the effectiveness of mailed CRC outreach education on completion of CRC screening, Singal AG, et al. [32] found that CRC screening was significantly increased among the mailed outreach group. In particular, FIT-based outreach was found to be more effective than colonoscopy-based outreach.

In another RCT, Meade CD, et al. [23] reported on experiences and lessons learned from implementing a lay patient navigator program to improve CRC screening completion among primary care medically underserved patients. Patient navigation was conducted by lay patient navigators and navigation services provided in six hospital-affiliated outpatient clinics and included barrier resolution services and helping to coordinate CRC care. Study population consisted of 588 Hispanic patients who predominantly spoke Spanish. The lay patient navigation program was effective in helping patients through a complex health care system. However, authors recommended a combination of lay and professional patient navigation to enhance coordination of CRC care, including completion recommended CRC screening. In an RCT conducted by Goldman S, et al. [9], 420 patients were randomized to either a PN outreach group or usual care. The goal of this study was to determine whether FOBT screening increased as a result of participating in the PN-led outreach intervention. Authors reported that intervention patients were significantly more likely to complete a fecal occult blood test compared to usual care (36.6 vs. 14.8%, p < 0.001, respectively). In addition, participants who visited the clinic often were more likely to complete the CRC screening test.

All cost-effectiveness studies included in this review have concluded that the use of patient navigation services as part of routine patient care are not only costeffective, but can also generate revenue due to CRC screening completion. For example, Jandorf L, et al. [17] in a cost-effectiveness analysis of a colonoscopy patient navigation program included data from 503 multi-ethnic primary care patients 50 years and older, randomized to either a professional health education group or a community-based peer navigation group. Patient navigator salaries, supply costs, and navigation time were included in the cost-effectiveness analysis. Patient navigation resulted in 78.5% of patients completing a colonoscopy. Cost-effective analysis revealed that the patient navigation program resulted in a profit for the institution over a two-year period.



Conclusions

Peer-reviewed publications consistently indicate a positive impact of patient navigation programs on CRC screening completion as well have provided preliminary evidence for their cost-effectiveness. More well-conducted studies are needed that explore the use of EHRs in promotion of timely CRC screening and outreach.

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