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Journal

Journal of the National Cancer Institute, 115(6)

ISSN

0027-8874

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Publication Date

2023-06-08

DOI

10.1093/jnci/djad032

JNCI: Journal of the National Cancer Institute, 2023, **115(6)**, 680–694
https://doi.org/10.1093/jnci/djad032
Advance Access Publication Date: 22 February 2023
Article

Characteristics of patient navigation programs in the Cancer Moonshot ACCSIS colorectal cancer screening initiative

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Abstract

Background: Although patient navigation has shown promise for increasing participation in colorectal cancer screening and follow-up, little evidence is available to guide implementation of patient navigation in clinical practice. We characterize 8 patient navigation programs being implemented as part of multi-component interventions of the National Cancer Institute's Cancer Moonshot Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science (ACCSIS) initiative.

Methods: We developed a data collection template organized by ACCSIS framework domains. The template was populated by a representative from each of the 8 ACCSIS research projects. We report standardized descriptions of 1) the socio-ecological context in which the navigation program was being conducted, 2) navigation program characteristics, 3) activities undertaken to facilitate program implementation (eg, training), and 4) outcomes used in program evaluation.

Results: ACCSIS patient navigation programs varied broadly in their socio-ecological context and settings, the populations they served, and how they were implemented in practice. Six research projects adapted and implemented evidence-based patient navigation programs; the remaining projects developed new programs. Five projects began navigation when patients were due for initial colorectal cancer screening; 3 projects began navigation later in the screening process, when patients were due for follow-up colonoscopy after an abnormal stool-test result. Seven projects relied on existing clinical staff to deliver the navigation; 1 hired a centralized research navigator. All project researchers plan to evaluate the effectiveness and implementation of their programs.

Conclusions: Our detailed program descriptions may facilitate cross-project comparisons and guide future implementation and evaluation of patient navigation programs in clinical practice.

Received: October 11, 2022. **Revised:** February 01, 2023. **Accepted:** February 13, 2023

Patient navigation is an evidence-based intervention that has been shown to substantially improve rates of colorectal cancer (CRC) screening and follow-up in numerous health-care settings in the United States (1-9). Despite evidence of effectiveness, widespread implementation of patient navigation has been limited, in part, due to the wide variety of approaches labeled as patient navigation and the lack of systematic description of patient navigation programs, the settings in which they have been implemented, and information on how to implement them in routine practice. Understanding common implementation challenges and ways to adapt programs to specific contexts can allow providers and decision-makers to overcome barriers and facilitate implementation in their unique settings (1).

Prior literature on patient navigation has identified key challenges to implementation, including incomplete and inconsistent reporting by studies implementing these programs on the contextual details, program characteristics, and strategies to support implementation. For example, in a systematic review of patient navigation for CRC screening, only one-third of studies (5 of 15) described the level of training received by the navigator (4).

A second challenge is the limited variety of contexts in which navigation programs have been carried out: most have been conducted in a single health system or clinic and/or in urban settings in the East Coast region of the United States (1,6). A recent meta-analysis showed a substantial increase in CRC screening (average relative increase in CRC screening of 64% among 28 studies that implemented patient navigation); however, substantial variation in effectiveness across studies limits confidence in the overall benefit (improvement range = 0.9–69.7 percentage points) (1). Effectiveness varied by study design, including whether the study used a randomized controlled trial or observational design, length of evaluation interval, and screening test outcome. As a result of underreporting of these details, little is known about how specific contextual factors, design features, and implementation strategies influence the effectiveness of patient navigation. This knowledge gap makes it difficult to translate patient navigation programs and anticipate their impacts in new settings (1).

As part of the Accelerating Colorectal Cancer Screening through Implementation Science (ACCSIS) consortium, a National Cancer Institute Cancer Moonshot Initiative, we applied the newly developed ACCSIS conceptual framework to the 8 ACCSIS research projects, all of which are testing patient navigation as part of multilevel interventions to improve rates of CRC screening, follow-up, and referral to care in diverse practice settings (10-13). For each navigation program, we sought to characterize 1) the socio-ecological context in which the navigation program was being conducted, 2) navigation program characteristics, 3) activities undertaken to facilitate program implementation (eg, training), and 4) outcomes used in program evaluation. In providing standardized descriptions of these patient navigation programs, our goal was to facilitate cross-project comparisons, guide future patient navigation program implementation and evaluation, and define potential unique contributions ACCSIS can make toward advancing patient navigation research and practice.

Methods

Setting and context

The ACCSIS consortium seeks to provide an evidence base for multilevel interventions that increase rates of CRC screening, follow-up, and referral to care and to identify best practices for scaling-up multilevel interventions to reduce the burden of CRC in the United States. The consortium consists of 8 research projects that were initiated over a 2-year period (Supplementary Table 1, available online). In the first year, 3 research projects were funded through the Cancer Moonshot Initiative (2019-2023); these projects were located in Kentucky and Ohio (Appalachian region), North Carolina, and Chicago. Three additional projects were funded in the first year (2019-2023) through separate Cancer Moonshot supplements to cancer center support grants; these projects were focused on American Indian populations in Arizona, New Mexico, and Oklahoma. Two additional research projects—located in San Diego and Oregon—were funded in the second year of ACCSIS (2020-2024). Consistent with the goal of generating practice-based evidence, the ACCSIS research projects were encouraged to incorporate pragmatic elements into their trial designs and analyses, as defined by the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) rating scale (14,15). PRECIS-2 is a validated rating scale that includes the following domains: eligibility criteria, recruitment, setting, organization, flexibility (delivery), flexibility (adherence), follow-up, primary outcome(s), and primary analysis (14).

ACCSIS conceptual framework

The ACCSIS conceptual framework identifies multilevel contextual factors that drive selection of and modifications to CRC screening interventions and implementation strategies (16). This framework is designed to serve as a model for how to implement CRC screening interventions and provides overarching guidance for selecting specific domains relevant to patient navigation. The framework was developed by a subgroup of ACCSIS investigators along with National Cancer Institute scientists and ACCSIS Coordinating Center scientists, using an iterative, consensus-building process.

The framework is divided into 3 phases: pre-implementation, implementation, and post-implementation. The pre-implementation phase centers on choosing interventions, describing the context in which the interventions are implemented, and preparing for implementation. The implementation phase describes the interventions and outcomes, both at the patient, provider, clinic, and community levels as well as short-term and long-term screening outcomes. Intervention impact analysis, equity assessments, and economic evaluations are in the post-implementation phase, as are dissemination of findings, intervention maintenance, and intervention scalability. For this report, we identified the following framework elements from the phases for each ACCSIS research project: socio-ecological context, program characteristics, implementation strategies, and evaluation outcomes.

Data collection

We define socio-ecological context as the geographic regions served, characteristics of health systems or clinics within health systems (ie, health system designation, available health system resources), patients (ie, demographic characteristics), colonoscopy providers (ie, availability of free or low-cost colonoscopy services), and community resources (ie, available resources) and policy context (ie, relevant policies such as certifications or insurance reimbursement). Program characteristics consisted of 6 subcategories: patient selection criteria (ie, age, due for CRC screening and/or follow-up colonoscopy), intervention selection characteristics (ie, whether the program was previously tested or newly developed), program characteristics (ie, program screening target, topic areas addressed, and the timing and format of process steps), delivery platforms (ie, phone, in-person, mail, text message), practitioner characteristics (ie, number of navigators,

their professional licensure, required and typical experience, the navigators' employer, and percentage full-time equivalent effort dedicated to navigation), and data tracking systems. Implementation strategies included navigator training topics and the amount (number of hours) and format of initial basic training and ongoing booster training or facilitation. Evaluation outcomes included primary and secondary effectiveness outcomes, implementation outcomes (ie, fidelity, acceptability, cost), and colonoscopy outcomes (ie, adenomas and cancers detected). We developed a template for data collection containing the individual variables within each of these 4 overarching domains. One or more representatives from each ACCSIS research project populated the template for their project between July 2021 and August 2022. Data were compiled into tables and refined through iterative discussions among members of the writing team.

In addition, the ACCSIS consortium previously defined common data elements for each research project; these data are stored in a centralized data repository, with public access for projects not working with American Indian populations. Common data elements specific to patient navigation included mode of contact (eg, in-person, telephone), barriers identified (eg, lack of transportation, lack of insurance), and services provided (eg, bowel preparation education, transportation assistance).

Results

Socio-ecological context

The ACCSIS patient navigation programs were implemented in broad geographic regions (Table 1) covering rural areas in 4 states (Oregon, Arizona, New Mexico, and Oklahoma), Appalachian areas (Ohio and Kentucky, North Carolina), and urban and suburban areas (San Diego, Chicago). The programs served diverse patient populations; the Oregon and Appalachia (Ohio and Kentucky) programs served mostly low-income, Non-Hispanic White populations, whereas the programs in San Diego, Chicago, and North Carolina served low-income and mostly Hispanic and African American populations served by federally qualified health centers. The programs in Arizona, New Mexico, and Oklahoma focused exclusively on American Indian populations. All programs included both men and women and initially focused on patients aged 50-75 years; over time, some projects expanded their age range to 45-75 years to align with updated screening recommendations (17). Populations at participating health centers and clinics varied in the proportion insured, from fully insured by Medicaid or dual Medicaid-Medicare coverage (Oregon) to predominantly uninsured (North Carolina).

In total, 120 clinics are involved in ACCSIS projects; the number of clinics per project ranges from 4 in New Mexico to 43 in Chicago. Some clinics practice independently, whereas many others are part of larger health systems. Resources available to assist patients with colonoscopy completion (eg, transportation assistance, financial assistance, case management) varied between clinics; clinics that were part of health systems generally had more resources than independent clinics, but resources available also considerably differed between health systems.

The number of colonoscopy facilities varied from 5 to 30 across projects. Some programs (eg, North Carolina, Oklahoma, and San Diego) have formed partnerships with local colonoscopy providers to perform reduced-rate colonoscopy and/or bowel preparation.

Another contextual difference between programs was the nature of state policies regarding certification for patient navigators (PNs). Of the states where the programs took place, only Oregon and New Mexico provide certification; however, the certification is only for community health workers (CHWs), who can bill for 1-on-1 educational services. Two research projects, New Mexico and Oklahoma, allow PNs and CHWs to receive continuing education credits for attending PN training.

Program characteristics

Table 2 summarizes patient navigation program characteristics. All programs delivered navigation to those with abnormal FIT test results, and 5 additionally offered navigation for initial CRC screening. Programs were either newly developed (New Mexico and Oklahoma), adapted from evidence-based programs (Chicago, Appalachia, Oregon, North Carolina, Arizona), or adapted from previous research by the study team (San Diego). The anticipated number of patients to receive patient navigation ranged from 25 to 2400 annually and corresponded with the scope of patient navigation services (ie, for screening or only follow-up) and the number and size of clinics.

Activities of the PNs were similar across programs (Supplementary Table 2, available online). Most PNs conducted barrier assessments, the hallmark of patient navigation, and assisted with scheduling, referrals, reminders, support, transportation, and insurance enrollment. Programs varied in the timing of navigation contact (immediately upon identification to up to 3 months after), primary mode of contact (phone, mailed and text reminders), and number of contacts before patients are considered unreachable (2-6). Two programs (Appalachia, North Carolina) consistently sent close-out letters for those who were not reached, were lost to follow-up, or declined participation; and 1 sent close-out letters for patients of some clinics (Oregon).

The number of PNs participating across the programs varied from 1 centralized PN (North Carolina) to 8 PNs (New Mexico), although 2 programs (New Mexico and Oregon) trained more than 30 PNs. Programs with more PNs used 1 or more PNs per health system or per clinic. No program required licensure for their navigators. Two programs required some experience in case management (Chicago) or prior experience with outreach or education (San Diego). PNs held a variety of job titles, including CHW, nurse, clinic manager, medical assistant, case manager, health coach, and health educator. In 7 programs, PNs were employed and supervised by a clinic or health plan; Chicago additionally used a vendor for text-based patient navigation, New Mexico also used PNs employed by tribal programs and organizations, and the North Carolina PN was employed by the academic cancer center where the program was conducted. All sites allowed PNs electronic health record (EHR) access; however, in New Mexico, clinic-based PNs, but not community-based PNs, had access.

Seven programs used mixed data tracking systems that involved both the EHR and study databases, whereas the Appalachia program solely used the clinics' EHR (except 1 clinic that also used an Excel file). All 8 studies tracked modifications to the patient navigation program, mostly using minutes from regular meetings, complemented in some cases by tracking tools (Arizona), clinic logs (Oregon), or periodic reflections and interviews with key implementers (Oregon and North Carolina). All sites with Hispanic populations included patient-facing materials in Spanish. A list of key materials used for patient navigation across all programs is provided (Supplementary Figure 1, available online).

Table 1. Description of the multilevel context for ACCSIS patient navigation components

Characteristics	Appalachia	Arizona	Chicago	New Mexico	North Carolina	Oklahoma	Oregon	San Diego
				Funding years				
Funding years	2019-2023	2019-2023	2019-2023	2019-2023	2019-2023	2019-2023	2020-2024	2020-2024
				Geographic regions served				
Geographic regions served	12 Appalachian counties in OH and KY	Largely rural AI communities in AZ	Cook County, IL; northern IN	Largely rural AI communities in Albuquerque area Southwest Tribal Epidemiology Center service area (NM and TX)	Northeastern and western NC	Rural southeastern and western OK and urban Oklahoma City	Rural and frontier communities in OR	San Diego County, CA
				Health system characteristics				
Health system	10 rural clinics	5 clinics (2 urban FQHC clinics, 3 IHS clinics)	4 health systems (43 clinics)	4 tribally operated clinics	2 FQHCs (16 clinics)	6 IHS/tribal/urban AI clinics	3 Medicaid health plans and 29 clinics (12 rural health clinics, 11 with no federal designation, 5 FQHC clinics, 1 tribal clinic) located in rural regions	3 FQHCs (9 clinics) and 1 centralized hub in urban and rural regions
Health system resources	Charity funds, hospital funding, HRSA funding, referral clerks for scheduling colonoscopy	PNs, support staff, appointment reminders, EHR notifications, limited transportation services	Case management/ care coordination team	Transportation services, appointment reminders, education, social support, interpretation	EHR queries; quality improvement team; hospital financial assistance; limited local transportation services (in 1 FQHC)	Clinic case managers, referral specialists, colonoscopy provided at IHS/tribal hospitals; primary care and tribal partners assist with transportation costs when needed	Health plan navigators will serve as backup for clinics, transportation benefit for Medicaid enrollees, low-cost colonoscopy services vary by clinic	Referral staff, physician prompts, EHR queries
				Demographic characteristics of population served by navigation[a]				
				Sex[a]				
Median % female (range)	51.5 (50-53)	59 (—)	59 (57-60)	50 (—)	58 (58-58)	56 (43-60)	53 (49-55)	59 (59-60)
				Insurance status[a]				
Median % uninsured (range)	2.5 (2-33)	—	17 (10-31)	30 (—)	23.5 (10-37)	29 (—)	0 (0-0)	20 (15-26)
Median % Medicaid (range)	31.5 (1-54)	—	56 (55-65)	70 (—)	8 (6-10)	10 (—)	100 (100-100)	60 (58-74)
				Race/ethnicity[a]				
Median % Non-Hispanic White (range)	99 (99-99)	0 (0-0)	37 (8-56)	0 (0-0)	53.5 (40-67)	0 (0-0)	93 (92-94)	30 (25-43)
Median % Hispanic American (range)	0 (0-0)	0 (0-0)	30 (10-37)	0 (0-0)	5.7 (0.4-11)	0 (0-0)	5 (4-7)	60 (54-77)
Median % Black/ African American (range)	0 (0-0)	0 (0-0)	45 (18-66)	0 (0-0)	30 (5-55)	0 (0-0)	1 (0-2)	5 (3-22)

(continued)

Table 1. (continued)

Characteristics	Appalachia	Arizona	Chicago	New Mexico	North Carolina	Oklahoma	Oregon	San Diego
Median % Asian American (range)	0 (0-0)	0 (0-0)	1 (1-2)	0 (0-0)	0.35 (0.3-0.4)	0 (0-0)	2 (1-2)	6 (3-17)
Median % American Indian (range)	0 (0-0)	100 (100-100)	0.5 (0-1)	100 (100, 100)	0.25 (0.2, 0.3)	100 (100, 100)	3 (2, 4)	1 (0,3, 1.0)
				Colonoscopy providers				
No. referring colonoscopy facilities	33	10-15	10-20	8	5-6	5	~20	20-30
Partnerships with colonoscopy providers	N/A	N/A	N/A	N/A	Reduced-cost colonoscopy services available ($500) at 1 FQHC for uninsured patients; fee covers provider-donated colonoscopy, preprocedure visit, anesthesia, pathology.	Tribal facilities (n = 3) and IHS facility (n = 1) provide bowel prep, colonoscopy free of charge to AI patients. Private GI practice (n = 1) charges standard rates for prep, colonoscopy.	Most providers are primary care providers trained to perform colonoscopies.	Reduced-cost colonoscopy services available ($800) and free colonoscopy services sometimes available through special programs
				Community resources				
Transportation services, limited	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Free/low-cost screening or follow-up, limited	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Overnight housing	No	Yes	No	No	No	Yes	No	No
Other	No	No	No	Educational materials, reminders for screening, social support	Interpretation services	Public service announcements (print, social media); community-based FIT distribution	No	No
				Policy context				
Relevant certifications/reimbursement	No certification requirements and no reimbursement for patient navigation services in KY or OH	No certification requirements and no reimbursement for patient navigation services	No certification requirements and no reimbursement for patient navigation services	Most community health workers certified by state departments of health and receive CEUs for attending trainings sponsored by study team	No certification requirements and no reimbursement for patient navigation services	No certification requirements: community health workers/navigators receive CEUs for attending trainings held in NM.	Certification offered to community health workers who can bill for 1-on-1 patient education; value-based payment, and capitated payment for patient-centered medical home status may help fund these roles.	No certification requirements and no reimbursement for patient navigation services in CA

[a] Medians and ranges are reported at the health plan-level for Oregon, at the helath center-level for San Diego, Chicago, and North Carolina, and at the clinic-level for Appalachia, Arizona, New Mexico, and Oklahoma. Medians and ranges were unavailable for some patient characteristics for Arizona, New Mexico, and Oklahoma. ACCSIS = Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science; AI = American Indian; FQHC = Federally Qualified Health Center; IHS = Indian Health Service; HRSA = Health Resources and Services Administration; PN = patient navigator; EHR = electronic health record; GI = gastroenterology; CEUs = continuing education units.

Table 2. Characteristics of ACCSIS patient navigation programs

Characteristics	Appalachia	Arizona[a]	Chicago	New Mexico[a]	North Carolina	Oklahoma[a]	Oregon	San Diego
				Patient selection criteria				
Eligibility for patient navigation[b]	Medically underserved adults	AI health system patients	Racial/ethnic minority and low-income populations	AI patients served by tribally operated health systems	Adults served by 1 of 2 partnering health systems	AI health system patients	Medicaid and dual (Medicaid-Medicare) recipients	Insured adults, served by 1 of 3 health systems
Age, y	50-74	50-75	50-74	50-75	50-74	50-75	50-75	50-75
Due for CRC screening	Yes	Yes	Yes	Yes	No	Yes	No	No
Due for follow-up to an abnormal stool-based test	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
				Intervention selection				
Previously published or newly developed protocol	Newly developed program or modification of existing program	Existing National Cancer Institute-funded navigation program, adapted to AI population (13)	New program and/or modifications of existing infrastructure (ie, text messaging)	Newly developed	Newly developed PN program informed by previous work and work of Newcomer (NC) and Pignone (TX) (42); PN protocols adapted from protocols developed by Dr Lynn Butterly (43)	Newly developed	Adapted PN program developed by Dr Lynn Butterly (43)	Based on previous work, scaled-up version (24)
Informed consent	Waived	Waived	Waived	Waived	Partially waived, verbal assent required	Waived	Waived	Waived
				Intervention characteristics				
Program target CRC screening	Yes	Yes	Yes	Yes	No	Yes	No	No
Follow-up to abnormal stool test	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Referral to care (as needed)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Anticipated no. patients to receive navigation (estimate)	3000 per year (150 per month [KY], 100 per month [OH])	~350 per year	720 per year (60-80 per month)	1300 per year (100 per month for CRC screening, 50-100 per year for follow-up colonoscopy)	40-50 per year (80 abnormal stool-test results FIT+ expected over 2 y)	2600 per year (200 per month for CRC screening, 15-20 per month for follow-up colonoscopy)	25 per year	100 per year
Topic areas	Identification, tracking, follow-up (5 clinics); identification, barrier assessment, tracking, follow-up (5 clinics)	Primarily phone-based navigation; reminders to complete FIT and/or abnormal FIT follow-up; assessment of barriers; education/outreach; interpretation; tracking of activities	Phone-based navigation: Step 1: Identification of patient (fail to complete screening after 60 d) Step 2: First phone call to assess barriers and social needs, provide	Primarily phone-based navigation; reminders to complete FIT and/or abnormal FIT follow-up; assessment of barriers; education/outreach; interpretation; tracking of activities	4-5 call protocol Call 1: Introduction and initial barrier assessment, schedule plans Call 1.5: Quick check-in to confirm whether patients are scheduled	Primarily phone-based navigation; reminders to complete FIT and/or abnormal FIT follow-up; assessment of barriers; education/outreach; interpretation; tracking of activities	4-topic protocol Topic 1: First call and barrier assessment (within 30 d of navigator assignment) Topic 2: Bowel prep review (7 d before colonoscopy) Topic 3: Colonoscopy	Phone-based navigation; abnormal FIT follow-up; assessment of barriers; assistance with colonoscopy prep and scheduling; assistance with appointment reminders and follow-up;

(continued)

Table 2. (continued)

Characteristics	Appalachia	Arizona[a]	Chicago	New Mexico[a]	North Carolina	Oklahoma[a]	Oregon	San Diego
			education as needed Step 3: Barrier resolutions Step 4 (Specific for colonoscopy): education on bowel prep Step 5: Colonoscopy check-in Step 6: Follow-up results (1 wk after FIT, 2-4 wk after colonoscopy)		Call 2: Review prep and reassess barriers Call 3: Final preprocedure check-in, final barrier assessment Call 4: Postprocedure check-in to review results and answer any remaining questions		check-in (day before colonoscopy) Topic 4: Colonoscopy results (1–2 wk after colonoscopy)	assistance with understanding diagnosis and cancer treatment, if needed; tracking of activities
Timing of program enrollment/initial patient navigator contact								
Immediately upon determination of eligibility	Yes	Yes	No, 1 wk after screening order through SMS; Phone navigation: 2 mo following stool test order or 3 mo following referral to colonoscopy	Yes	Yes	Yes	Yes	Yes
Patient identification/eligibility confirmation	EHR query (for CRC screening and follow-up) followed by manual scrub; also monitor annual wellness visit lists	EHR query and clinic scheduling system	EHR query or population management tool	EHR query	EHR query, followed by manual scrub of CRC results at 1 clinic, eligibility confirmation via intro letter with study information allowing patients to self-report screening history	EHR query	Manual review of FIT results (of enrollees included in annual mailed FIT program); clinic staff confirm eligibility	EHR query
Introduction letter sent?	No	No	No	No	Yes	No	No	No
Delivery platforms								
Phone	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
In-person	Yes	Yes	No	No	No	No	No	No
Mail	Yes	No	Yes	Yes	Yes	Yes	No	No
Text	No	No	Yes	No	No	Yes	No	No
Patient contacts (no. attempts)	At least 2 attempts	From 1 (if person declines/requests no more contact) to 6 before lost to follow-up	2 phone calls and postcard for FIT/screening colonoscopy	Up to 5 call attempts	~4 calls for navigated patients, ~3 attempts for unable to reach and/or lost to follow-up	~3 calls or mailings; varies by clinic	Determined by clinic	At least 5 attempts
Close-out letter sent for not reached, declined, or lost to follow-up (programmatically)?	Yes	No	No	No	Yes	No	No, but clinics can opt to send close out letter as part of standard care	No, recorded in EHR as unable to notify/locate patients who need abnormal FIT follow-up

(continued)

Table 2. (continued)

Characteristics	Appalachia	Arizona[a]	Chicago	New Mexico[a]	North Carolina	Oklahoma[a]	Oregon	San Diego
				Practitioners				
No. navigators	16 (9 clinics have 1 PN, 1 clinic has 7 PNs)	5 (1 per site) funded by the grant	4 (1 per health system) plus text-based client reminder and education system	6-8 PNs trained per clinic, at least 2 deployed per clinic	1 + 1 back-up PN, centralized	10 trained, 5 deployed (1 system with 3 clinics has 1 PN, 1 system with 2 clinics has 1 PN, 1 system with 1 clinic has 1 PN; 2 PNs work on community outreach for all study clinics)	31 (~2 per clinic) plus 1 back-up navigator (at health plan-level) trained; 6 deployed	3 (1 per health system)
Professional license required?	No	No	No	No	No	No	No	No
Experience required for PN role?	No	No	Case management experience	No	No, but experience preferred	No	No	Yes. Associate degree in related field plus 3 y relevant experience
Typical licensure/experience/position	Case managers, population health nurses, nurse navigators, health coach	CHWs and clinic staff	Case managers, CHWs	Medical assistants, nurses, nurse practitioners, CHRs, public health nurses, nursing assistants, health educators	N/A	Registered nurses, licensed practical nurses, or community health educators	Clinic manager, registered nurse, medical assistant, CHW	CHW, medical assistant, case manager, health educator, PN
Navigators' employer	Health system	Clinic	Partner health systems (traditional PN) and by university for text-based navigation	Tribes and tribally operated clinics	Academic cancer center employee using ACCSIS research funds	IHS/tribal/urban Indian clinic facility; 2 PNs employed by OK University College of Nursing serve as hub for all PNs	Clinic or health plan	Clinics
% FTE dedicated to navigation	5%-100%	100%	5%-50%	25%	100%	100%	<5%	100%
				Data tracking systems used (for navigation)				
Research-specific database (REDCap or Excel)	Yes (1 clinic)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Other	No	No	Yes, EHR reports; automated text message reminder platform	Yes, lab logs	No	No	Yes, Medicaid claims data	No

[a] All tribal members can access health-care services at the tribally operated health-care facilities; some clinic sites are tribally operated and thus are part of the community. AI = American Indian; CRC = colorectal cancer; PN = patient navigator; FIT = fecal immunochemical test; SMS = short message service; EHR = electronic health record; CHW = community health worker; CHR = community health representative; ACCSIS = Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science; IHS = Indian Health Service; FTE = full-time equivalent.

[b] Eligibility criteria were modified for some programs to align with 2021 US Preventive Services Task Force recommendation to initiate CRC screening at age 45 years.

Training and education implementation strategies

Table 3 displays the training and education implementation strategies for the patient navigation programs. All PNs were trained in navigation procedures, data-tracking procedures, and CRC screening and follow-up. Navigator training varied in duration across sites, ranging from 1 hour to 2.5 days, and involved a variety of formats, including webinars, in-person training, and pre-recorded videos. Training was didactic at some sites and self-directed at others. Implementation strategies also varied by site: the Oregon program held monthly meetings, the San Diego program conducted technical assistance, and several sites offered refresher or booster training as needed. Session frequency ranged from biweekly to as-needed.

Evaluation outcomes

All programs are assessing effectiveness outcomes, implementation outcomes, and colonoscopy outcomes (Table 4). All programs anticipate reporting all identified outcomes (defined individually by each site), with some exceptions: the Oregon program is not reporting time spent and cost analyses, and colonoscopy quality is being collected in just 2 sites, San Diego and North Carolina.

Discussion

Despite evidence supporting patient navigation as an approach to improve CRC screening and follow-up, little evidence is available to guide the implementation of patient navigation in diverse practice settings. Evaluation of patient navigation programs has reported broad variation in effectiveness according to key design and evaluation features. Yet, prior evaluations have insufficiently and inconsistently reported contextual factors and implementation strategies that may drive successful outcomes. Our framework-guided description of the 8 ACCSIS patient navigation programs, including their socio-ecological context, program features, implementation strategies, and evaluation outcomes, fills a critical literature gap and can guide future patient navigation program implementation and evaluation.

Our report shows heterogeneity in the socio-ecological contexts of the programs, with considerable variation in geographic and health care settings, populations served, and state policies relating to certification and reimbursement for navigation-related services. We observed similarities across programs in the activities performed by PNs yet broad variation in implementation strategies. Outcomes for planned evaluations were similar across sites. The heterogeneity in socio-ecological context and implementation strategies, together with similarity in PN activities and evaluation measures across programs, should allow the collective findings to apply to a wide range of settings and contexts and should facilitate comparisons across projects to identify important considerations for effective implementation of patient navigation in specific contexts.

A distinguishing feature of the ACCSIS patient navigation programs compared with programs evaluated in most prior reports is that they are more embedded into standard clinical care. Among 22 randomized controlled trials included in a recent systematic review and meta-analysis (1), only 7 (32%) (18-24) reported obtaining a waiver of written informed consent from their institutional review boards [of these, 2 obtained verbal consent (19,23)], indicating a pragmatic study design (PRECIS domain: eligibility criteria) (14). Of the 9 studies that administered written informed consent included in the review, the median proportion of participants who consented was 70% (range = 57%-91%) (25-33). Patients who consent to research are often more willing to participate in preventive health screening than patients who decline participation, raising the possibility of selection bias and overestimating effect sizes for outcomes of interest. In contrast, all ACCSIS sites obtained a waiver of written informed consent for their navigation programs (1 site administered verbal assent), likely resulting in greater representativeness of participants and generalizability of findings (34). By estimating the effectiveness of patient navigation when implemented in real-world practice settings, these projects can provide needed high-quality evidence to inform clinical practice guidelines and clinical decision making. Future research might assess these programs across other PRECIS domains, such as recruitment, setting, organization, flexibility (delivery), flexibility (adherence), follow-up, primary outcome(s), and primary analysis (14).

ACCSIS seeks to advance patient navigation research and practice by leveraging both the common and distinct features of our programs. All ACCSIS research projects are collecting common data elements to facilitate cross-project analyses. For example, programs can be compared based on mode of contact and services provided, and patient barriers can be compared across program populations. The present report may facilitate broader cross-project comparisons. For example, we provide more detail than in most prior reports on the contextual factors related to incentives and infrastructure to support patient navigation (ie, reimbursement policies, certification programs), and strategies to support program implementation. When comparing implementation outcomes across the 8 programs, it will be possible to explore how these contextual factors may have contributed to implementation success.

Prior research has identified potential innovations to improve patient navigation programs, including increasing health system colonoscopy capacity and using low-cost reminder systems together with patient navigation (8,35). ACCSIS programs vary in implementation of these innovations (eg, in Oregon, colonoscopy is often performed in rural settings by primary care providers, and the Chicago-based program combines patient navigation with automated text message reminders timed to the colonoscopy appointment), providing potential opportunities to advance research on the impacts of these innovations.

The findings from our consortium can be applied across a range of programs, including current or future CRC screening or follow-up programs, as well as patient navigation programs beyond CRC. For example, the consistent capture and reporting of contextual factors and implementation strategies could advance research on patient navigation for other cancer screening and follow-up targets. Moreover, innovations and adaptations introduced in response to contextual factors may have broad applicability. Given that cost is a known barrier to implementing and sustaining patient navigation programs, identifying successful adaptations can lead to the efficient selection of design features that can support long-term program sustainment. Moreover, it may become increasingly important to understand the role of patient navigation to ensure follow-up colonoscopy completion as new first-line screening modalities (eg, blood tests or urine tests) become available (36).

The ACCSIS consortium includes many navigation programs that vary in their socio-ecological contexts, program designs, and implementation strategies. We applied a unifying framework to characterize these programs in a way that will facilitate future understanding and comparison of program outcomes.

Table 3. Training and education implementation strategies for ACCSIS patient navigation programs[a]

Characteristics	Appalachia	Arizona	Chicago	New Mexico	North Carolina	Oklahoma	Oregon	San Diego
				Training and education implementation strategy				
Patient navigation training topics	Voluntary self-directed web-based training https://www.cecentral.com/node/1466 with continuing education credits Informal training delivered during implementation planning, clinic orientation, and on-the- job training	9 modules (M) M1: CRC 101 M2: Epidemiology of CRC among AI M3: CRC screening guidelines M4: Stool-based CRC screening tests M5: Direct visualization CRC screening tests M6: CRC risk factors M7: CRC diagnosis and treatment M8: Stages of change and motivational interviewing M9: Patient navigation tips; Initial navigator training conducted in partnership with NM and OK; AZ-specific training addressed data tracking	3 modules M1: CRC screening and surveillance:1 h M2: social needs assessment and patient education skills:1 h M3: intake process and available resources:1 h	Same 9 modules as AZ	Self-directed training using navigation toolkit (Lynn Butterly) and other web-based modules; webinars on effective patient navigation; motivational interviewing training	Same 9 modules as AZ	4-module core training program: M1: Patient navigation and colon health (pre-recorded videos): 1 h M2: Effective messages and script review (interactive virtual class): 1.5 h M3: Practice (interactive virtual class): 1.5 h M4: Data tracking (webinar): 1 h Optional module: motivational interviewing (pre-recorded videos): 1 h	Review of ACCISS protocol via video-conference (using handouts): 1.5 h Review of data materials: 1 h Booster sessions as needed
Training time	1 h plus online	2 d plus 6 h	3 h	2.5 d	Variable	2.5 d	4 h core/1 h optional	2.5 h/additional as needed
Training format	In-person or video-conference, and online	In-person	Videoconference	In-person	Toolkit review and web-based modules	In-person	Pre-recorded videos, live video-conference; training materials and evaluations hosted on learning management system	Video-conference

(continued)

Table 3. (continued)

Characteristics	Appalachia	Arizona	Chicago	New Mexico	North Carolina	Oklahoma	Oregon	San Diego
Refresher training format	Uses training materials and 1-on-1 assistance by study staff	Half-day session held virtually or in-person	Ongoing 20-min booster training during routine care management team meetings; providers are reminded to tell their patients receiving FIT that they will be enrolled in a text messaging platform	Refresher trainings in community or clinic-based settings, ranging from 2 h (in-person) to half-day (webinar)	Meetings with patient navigation workgroup, physician consultation available (including GI) at cancer center; consultation with clinic providers and medical directors as needed; periodic consultation with PNs from other institutions	2 half-day sessions; initially in person but shifted to virtual format post-COVID	Meetings held with Medicaid health plan staff, clinic staff (including PNs), and research team; 1-on-1 support available from practice facilitators; PNs can access asynchronous training videos as needed on learning management system	Health Quality Partners provides technical assistance and responds to inquiries via email
Refresher training frequency	As needed	Annual	Every 4 mo	3/y	Weekly/as needed	As needed	Monthly learning collaboratives, asynchronous training videos, ad hoc practice facilitation	Bi-weekly/as needed

[a] ACCSIS = Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science; M = module; CRC = colorectal cancer; AI = American Indian; FIT = fecal immunochemical test; GI = gastroenterology; PN = patient navigator.

Table 4. Analytic plan and outcomes of ACCSIS patient navigation programs[a]

Characteristic	Appalachia	Arizona	Chicago	New Mexico	North Carolina	Oklahoma	Oregon	San Diego
				Effectiveness outcomes				
Primary effectiveness outcome	Any CRC screening within 12 mo; colonoscopy completion within 6 mo of abnormal stool test result	Any CRC screening completed within the year	Any CRC screening completion within 9 mo	Any CRC screening within 12 mo; colonoscopy completion within 6 mo of abnormal stool test result and, if necessary, CRC treatment	Colonoscopy completion within 6 mo of abnormal stool test result	Any CRC screening within 12 mo; colonoscopy completion within 3 mo of abnormal stool test result and, if necessary, CRC treatment initiated within 3 mo	Colonoscopy completion within 6 mo of abnormal stool test result	Colonoscopy completion within 6 mo of abnormal stool test result
Secondary effectiveness outcomes	Time to follow-up colonoscopy	Time to follow-up colonoscopy, colonoscopy results, CRC management outcomes	Time to screening completion (from order/referral)	Time to follow-up colonoscopy; time to first treatment evaluation following CRC diagnosis; CRC treatment outcomes	Time to follow-up colonoscopy; neoplasia detection; adequacy of bowel prep	Time to follow-up colonoscopy; time to first treatment evaluation following CRC diagnosis; CRC treatment outcomes	Time to follow-up colonoscopy; colonoscopy referral within 6 mo of abnormal stool test result	Time to colonoscopy after abnormal FIT; colonoscopy quality; follow-up process; neoplasia detection
				Implementation outcomes				
Program fidelity assessed	Yes	Yes, tracked in database	Yes	Yes, recorded in multisector action team meeting minutes and will be included in monthly data reports	Yes, % delivered partial navigation, % not reached, % ineligible	Yes, tracked in monthly data reports	Yes, % delivered full navigation (all 4 topic areas), partial navigation, % not reached, % ineligible	Yes
Acceptability, clinic-level	Yes	Yes	Yes	Yes, changes in facility readiness to change	No	Yes, changes in facility readiness to change	Yes	Yes
Acceptability, patient-level	No	No	Yes, patient satisfaction	No	Yes, patient satisfaction	No	Yes	Yes, patient satisfaction
Adaptations tracked and documented	Yes	Yes, discussed in monthly meetings and tracked internally	Yes	Yes, recorded in multisector action team meeting minutes	Yes, and reasons for adaptations	Yes, discussed as regular agenda item in weekly project meeting calls	Yes, using call logs and periodic reflections	Yes

(continued)

Table 4. (continued)

Characteristic	Appalachia	Arizona	Chicago	New Mexico	North Carolina	Oklahoma	Oregon	San Diego
Time spent/cost analysis	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Reach of patient navigation, assessed (if so, how defined)	Yes, n FITs sent; n calls made; n FITs returned (complete and able to be processed by lab); n pts requiring follow-up for abnormal tests	Yes, n contact attempts with patients and type of interaction	Yes, % of patients who did not complete their FIT in 2 month or colonoscopy in 3 months and received patient navigation (ie, have a conversation with PN and the interaction is recorded in the encounter form)	Yes, n patients reached, attempts with patients and type of interaction	Yes, n, %, and representativeness of patients with a positive FIT who participate in at least 1 navigation call among all patients with a positive FIT in study intervention arm	Yes, n patients served by practice, % eligible for screening sent FIT cards by PN; % patients with positive screens whose diagnostic colonoscopy was facilitated by the PN; % patients with cancer whose cancer treatment was facilitated by the PN.	Yes, n, % who are left a message or have a personal conversation with navigator	Yes, n patients in intervention clinics in need of abnormal FIT follow-up
				Colonoscopy outcomes				
Colonoscopy findings tracked	Yes, n, % normal, with adenomas, or cancer	Yes, n, % normal, with adenomas or cancer	Yes, n, % normal, with adenomas, advanced adenomas, or cancer	Yes, n, % normal, adenomatous or serrated polyps, cancer, other diagnosis	Yes, n, % normal, adenomatous or serrated polyps, cancer, other diagnosis	Yes, n, % normal, adenomatous or serrated polyps, cancer, other diagnosis	Yes, n, % normal, with adenomas, advanced adenomas, or cancer	Yes, n, % normal, with adenomas, advanced adenomas, or cancer
Colonoscopy quality	No	No	No	No	Yes, bowel prep adequacy, cecum reached	No	No	Yes, bowel prep adequacy, cecum reached

[a] ACCSIS = Accelerating Colorectal Cancer Screening and Follow-Up Through Implementation Science; CRC = colorectal cancer; FIT = fecal immunochemical test; PN = patient navigation.

There are several limitations to this descriptive report that should be considered. First, our descriptions reflected baseline characteristics, and further modification to some variables will likely occur in some programs. Moreover, all ACCSIS patient navigation programs are part of larger multilevel interventions focused on CRC screening, follow-up, and referral to care, and some programs are designed to only provide navigation to a small number of participants. Our report does not evaluate which components or combinations of components are the most effective for improving CRC screening and follow-up. It also does not specifically capture COVID-19–related adaptations, though the impact of COVID-19 on colonoscopy capacity has been well documented (37-41). These could be topics for future research involving the ACCSIS consortium.

The ACCSIS consortium is implementing and evaluating 8 patient navigation programs in diverse health-care settings and geographic regions of the United States. Collective evaluations of these programs will build a new body of practice-based evidence on designing, implementing, evaluating, and sustaining patient navigation programs to improve CRC screening, follow-up, and referral to care in diverse health-care settings. The characteristics of each of these patient navigation programs, as identified here, provide context for those future analyses as well as provide guidance for those currently planning to implement a patient navigation program in any setting.

Data availability

The data underlying this article are available in the article and in its online supplementary material.

Author contributions

Gloria D. Coronado, PhD (conceptualization; data curation; investigation; methodology; project administration; writing—original draft); Sujha Subramanian, PhD (project administration; writing—review and editing); Daniel S. Reuland, MD, MPH (data curation; writing—review and editing); Jill M. Oliveri, MPH (data curation; writing—review and editing); Wynne E. Norton, PhD (writing—review and editing); Jesse N. Nodora, PhD (conceptualization; data curation); Shiraz I. Mishra, MBBS, PhD (data curation; writing—review and editing); David Liebovitz, MD (data curation; writing—review and editing); Sarah Kobrin, PhD (writing—review and editing); Karen E. Kim, MD (data curation; writing—review and editing); Jenna Hatcher, PhD, MPH (data curation; writing—review and editing); Kevin English, DrPH (data curation; writing—review and editing); Mark Doescher, MD, MSPH (data curation; writing—review and editing); Melinda M. Davis, PhD, MCR (data curation; writing—review and editing); Mark Cromo, BS (data curation; writing—review and editing); Sheila F. Castañeda, PhD (data curation; writing—review and editing); Autumn Barnes, BA (project administration; writing—review and editing); Renée M. Ferrari, PhD, MPH (conceptualization; data curation; investigation; project administration; writing—original draft); Jamie H. Thompson, MPH (data curation; writing—review and editing); Electra Paskett, PhD (conceptualization; data curation; investigation; project administration; writing—original draft).

Funding

Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Numbers UG3/UH3CA244298 (Oregon), UG3/UH3-CA233251 (North Carolina), UG3/UH3CA233314 (San Diego), P30CA118100-16S4 (New Mexico), U24CA233218 (RTI), UG3/UH3CA233282 (Appalachia), P30CA225520-03S4 (Oklahoma), UG3/UH3CA233229 (Chicago), P30CA023074-40S2 (Arizona).

Conflicts of interest

From 2020 to present, Dr Coronado has served as a scientific advisor on contracts with Exact Sciences and Guardant Health through the Center for Health Research. Dr Paskett is the MPI on grants to Ohio State University from Merck Foundation, Pfizer, and Genentech for work not related to this study. All other authors declare no conflicts of interest.

Acknowledgements

The funder had no role the study design; data collection, analysis, or interpretation; the writing of the manuscript or decision to submit it for publication. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Clinicaltrials.gov registration numbers: Oregon: NCT04890054, North Carolina: NCT044067, San Diego: NCT04941300, Appalachia: NCT04427527, Chicago: NCT0451434, Oklahoma: Not registered, Arizona: Not registered, New Mexico: Not registered.

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