





















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.

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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 | 2019-2023 | 2019-2023 | 2019-2023 | Funding years 2019-2023 | 2019-2023 | 2019-2023 | 2020-2024 | 2020-2024 |
| Geographic regions served | 12 Appalachian counties in OH and KY | Largely rural AI communities in AZ | Cook County, IL; northern IN | Geographic regions served 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 | 10 rural clinics | 5 clinics (2 urban FQHC clinics, 3 IHS clinics) | 4 health systems (43 clinics) | Health system characteristics 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) |
| 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, prep procedure 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 |
| 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 |
| 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 health 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 | |
|---|--|---|---|---|--|---|---|---|---|
| Eligibility for patient navigation ^b | Medically underserved adults | AI health system patients | Racial/ethnic minority and low-income populations | Patient selection criteria 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 | |
| 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) | Intervention selection 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) Timing of program enrollment/initial patient navigator contact | | 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 |
| 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 |
|--|---|------------------------------------|---|---|---|--|--|---|
| 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 | Practitioners 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% |
| Research-specific database (REDCap or Excel) | Yes (1 clinic) | Yes | Yes | Data tracking systems used (for navigation) | | 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 | |
|------------------------------------|--|---|--|---|---|---|---|--|---|
| 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 | Effectiveness outcomes | | | | | |
| 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) | Any CRC screening within 12 mo; colonoscopy completion within 6 mo of abnormal stool test result and, if necessary, CRC treatment | Time to follow-up colonoscopy; time to first treatment evaluation following CRC diagnosis; CRC treatment outcomes | 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 | Time to colonoscopy after abnormal FIT; colonoscopy quality; follow-up process; neoplasia detection |
| Program fidelity assessed | Yes | Yes, tracked in database | Yes | Implementation outcomes | | | | | |
| Acceptability, clinic-level | Yes | Yes | 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 | Yes |
| Acceptability, patient-level | No | No | Yes, patient satisfaction | No | Yes, patient satisfaction | No | Yes | Yes, patient satisfaction | 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 | 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 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 | Colonoscopy outcomes 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).

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Conflicts of interest

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