## Title

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# Evaluating the implementation and impact of a volunteer navigation oncology support programme: study protocol for a pragmatic, real-world hybrid type 2 study

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## ABSTRACT

**Introduction** Patient navigation is recommended by accrediting bodies such as the Commission on Cancer and is a key element in payment reform demonstration projects, due to the established benefits in reducing barriers to healthcare, improving care coordination and reducing healthcare utilisation. However, oncology practices are often resource constrained and lack the capacity to extend navigation services at the desired intensity for their patient population. The American Cancer Society (ACS) developed the ACS Community Access to Resources, Education, and Support (CARES) programme to expand navigation capacity through the training of students from local universities as volunteers to serve as non-clinical navigators to support cancer patients. Although this approach has great potential for scalability, the best approach to early implementation and impact of volunteer navigation remains unclear.

**Methods and analysis** This pragmatic single-arm pre–post study evaluates the implementation and effectiveness of volunteer navigation for patients participating in the 2023–2024 pilot. This study will use data collected during routine care for quantitative implementation and patient outcomes. The Updated Consolidated Framework for Implementation Research will guide evaluation of early programme implementation with three initial pilot sites. This pragmatic evaluation of real-world implementation of volunteer navigation in the oncology setting will support future efforts to scale-up this intervention across US health systems.

**Ethics and dissemination** This study was approved by University of Morehouse School of Medicine Social and Behavioral (IRB), which served as the IRB for record for this project (IRB-2025819–2). No consent required for this study protocol. ACS CARES plans to disseminate this model and include additional sites as participants in future years.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Facilitates systematic identification of factors promoting effective uptake and sustainability of interventions.
⇒ Allows thorough analysis of both barriers and facilitators in the adaptation process.
⇒ Study included a limited number of providers.
⇒ Additional insights may be gained with more participants.
⇒ Provides a solid foundation for replicating and scaling successful practices.

## INTRODUCTION

Patient navigation is a well-established intervention that improves patient access, timeliness of care, communication and utilisation outcomes. Increasingly, health systems are successfully using individuals without a clinical license (peer navigators, community health workers) to expand navigation capacity. At the University of Alabama at Birmingham, non-clinical navigation within the health system was associated with high satisfaction; reduced emergency room visits, hospitalisations, intensive care unit (ICU) admissions; and decreased cost to payers.[1–3] In work conducted by Patel *et al*, community health worker interventions demonstrated improved time to treatment, participation in clinical trials, documentation of advance care planning, quality of life, reduced utilisation, reduced cost.[4–7] With mounting evidence from multiple programmes and systematic reviews, little controversy exists about the benefits of and the need for navigation services.[8] However, despite these benefits, programmes like those described above are not universal. Payment for navigation has been elusive with practices relying on philanthropic funds and institutional support, and there remains a need to provide a strong business case for navigation.[9] Furthermore, even in centres providing navigation services, there

are inherent capacity issues related to a limited workforce. Thus, programmes commonly target their intervention to a subset of the patient population rather than being able to provide optimal navigation to all patients.

One potential approach to expanding navigation capacity is to consider an adjunctive intervention, which can be defined as 'change methods' for interventions that are intended to increase implementation outcomes such as the capacity for initiating the intervention and maintaining this over time.[10] On such approach is to engage volunteers to support navigation efforts. This model has been successfully deployed at Atrium Health Wake Forest Baptist Comprehensive Cancer Center since 2012 in a programme called *Take the Fight to Cancer*.[11 12] This programme trains students to provide non-clinical navigation services, which can be delivered in conjunction with the existing professional navigators (clinical and non-clinical). Within this model, the cancer system increased capacity and the students are provided needed exposure to the healthcare system and mentorship as part of their interactions with members of the clinical team that can support interest in careers in healthcare. In another application at the University of North Carolina at Chapel Hill, volunteers of all ages provided navigation support for patients with cancer since 2014.[13] Although these programmes have not been formally evaluated in the research context for implementation outcomes or effectiveness, they highlight the potential for volunteers to work within the context of health systems to support navigation of patients with cancer.

In 2023, the American Cancer Society (ACS) created a new programme, ACS Community Access to Resources, Education, and Support (CARES), based on coauthor (BM, CW, GBR) experience implementing Take the Fight to Cancer and lay navigation programmes as well as existing literature on non-clinical navigation. The goal of ACS CARES is to supplement existing navigation infrastructure to extend navigation services for increased depth of support to a broader population of patients. This is accomplished through designating lower-level, timely tasks to volunteers and allowing paid navigators to practice at the highest level of their license (eg, nurses providing symptom management, higher-level coordination). The goal of this study is to evaluate the pilot phase of ACS CARES to identify key implementation outcomes and assess effectiveness of the programme to improve distress, enhance communication and reduce missed appointments and healthcare utilisation.

## METHODS AND ANALYSIS

### Patient involvement statement

Patients played a crucial role in the development and implementation of the ACS CARES programme. Their experiences and feedback were instrumental in identifying the barriers to healthcare and the need for improved care coordination, which the programme aims to address.

### Study design

This pragmatic, pre–post design study leverages the hybrid type 2 study design,[14] to concurrently evaluate the implementation and effectiveness of volunteer navigation within the ACS CARES programme. The programme launched in September 2023. This study focuses primarily on implementation outcomes given the novel nature of the programme and limited feasibility data on this approach and a limited number of providers engaging with the ACS CARES programme. Although a preliminary assessment of effectiveness is included, this is intended to inform future studies that will focus on effectiveness. At the time of manuscript submission, all three sites have launched the programme. Initial data collection is ongoing and will continue through September 2024. This real-world study will have four key components: (1) implementation outcomes; (2) health system and utilisation outcomes; (3) volunteer satisfaction and (5) patient-reported outcomes (table 1).

The analysis will predominantly use data captured as part of routine care and delivery of the navigation intervention, except for a cross-sectional survey on patient and volunteer experience.

This study was approved by a central Institutional Review Board from Morehouse University, which served as the IRB for record for this project with secondary approval from the University of Alabama at Birmingham.

### Implementation setting

Three initial sites were included in this early implementation phase: the University of Iowa, the University of California at Los Angeles (UCLA), and the Medical University of South Carolina (MUSC). Each location identified a clinic with physician champions for the initial rollout. The University of Iowa Hospitals and Clinics (UIHC) is the tertiary care, academic medical institution in the state of Iowa, which serves the majority of the state of Iowa as well as many patients from western Illinois and other surrounding midwestern states. Holden Comprehensive Cancer Center (HCCC) is the matrix cancer centre at UIHC. HCCC provides patient care on the main hospital campus is delivered across five adult and one paediatric outpatient clinics, two infusion suites, a stem cell transplant and cellular therapy unit and inpatient nursing units as well as through outreach clinics across the state. In FY23, patients were seen from all 99 counties in Iowa as well as 36 US states and had over 100 000 annual visits to the clinical cancer centre and infusion suites. The ACS CARES programme will be implemented in the Gynecologic Oncology Clinic. The UCLA Health Jonsson Comprehensive is a designated Comprehensive Cancer Center by the National Cancer Institute (NCI) and part of the National Comprehensive Cancer Network (NCCN). UCLA Health Jonsson Comprehensive Cancer Center serves the entire cancer population of Los Angeles County (>20 million) from children through adulthood through its four hospital locations and over 100 ambulatory clinics. The ACS CARES program at UCLA will be

**Table 1** Summary table of study metrics

| Outcome | Concept | Data source | Evaluation metrics | Timing |
|---|---|---|---|---|
| Component 1: Context, training and process measures | Context | Field notes | ► # of clinical and nonclinical navigators (including oncology social workers) at each participating site<br>► # of clinical providers and clinics engaging with ACS CARES volunteers at each site<br>► barriers and facilitators identified in implementing the pilot programme<br>► date and details of any changes, team staffing or organisation, institutional policy changes, and national policy changes that we anticipate will impact the ACS CARES programme | Baseline, mid-year and 1 year |
| | Volunteer onboarding | ACS volunteer management system | ► # and % of students who complete ACS requirements to volunteer<br>► # and % of students who complete health system requirements to volunteer<br>► # and % of volunteers who complete all training<br>► # and % of volunteers who do not complete all training<br>► # of synchronous trainings conducted<br>► time to complete the overall ACS onboarding process<br>► time to complete health system-specific training<br>► time to complete online ACS CARES navigation training modules<br>► # of continuing education sessions conducted | Volunteer onboarding period, prior to volunteer launch |
| | Service penetrance | ACS data management platform | ► # of patients/caregivers approached for ACS CARES<br>Median and range per volunteer<br>► # of patients/caregivers who decline by refusal reason<br>► # of patients/caregivers supported by ACS CARES<br>Median and range per volunteer<br>► # of patients/caregivers who received psychosocial distress screening<br>Median and range per ACS CARES volunteer<br>► # of patients/caregivers who received an SDOH screening<br>Median and range per ACS CARES volunteer<br>► # of follow-ups conducted<br>Median and range per ACS CARES volunteer<br>► # of in-person visits conducted<br>Median and range per ACS CARES volunteer<br>► # of shifts completed<br>Median and range per ACS CARES volunteer<br>► # of referrals received from health system team members | Monthly; and sum of the programme |
| | Volunteer satisfaction | ACS volunteer survey | Volunteer Satisfaction Index | 1 year |
| | Implementation blueprint | Summary results of context, training and penetrance data | N/A | 1 year |
| Component 2: Sociodemographic differences between ACS CARES supported and non-ACS CARES supported patients; impact of ACS CARES on treatment adherence and healthcare utilisation | Acceptability, effectiveness | Pilot site health system report | Patient characteristics: age, sex, gender (if available), race, ethnicity, insurance status, zip code, urban or rural residence, Area Deprivation Index category, and distance from cancer centre (<30 min, 30–60 min >60 min)<br>Cancer and treatment characteristics: cancer type, date of diagnosis, type of current treatment (surgery, chemotherapy, radiation therapy, targeted therapy, immunotherapy, stem cell or bone marrow transplant, hormone therapy), total clinic appointments, # clinic appts missed/cancelled, total infusion appointments, # infusion appointments missed/cancelled, total radiation treatment appts, # radiation treatment appointments missed/cancelled, enrolled in a clinical trial (y/n), start date of clinical trial participation, ER visits, hospitalisations, ICU admissions, total cost of care. For new patients during baseline or intervention time periods, date of first clinic visit. | Baseline (1 January 2022 to 31 December 2022) and Intervention (1 September 2023 to 31 August 2024) |
| Component 3: Measure the impact of ACS CARES on patient-reported outcomes | Acceptability, effectiveness | ACS NurseNav data management platform<br>ACS survey | Distress, information needs, SDOH barriers, satisfaction with programme, unmet needs, patient–provider communication, clinical trials knowledge, patient activation, financial toxicity, quality of life | Baseline and 6 months into pilot |

ACS CARES, American Cancer Society Community Access to Resources, Education, and Support; ER, emergency room; ICU, intensive care unit; SDOH, social determinants of health.

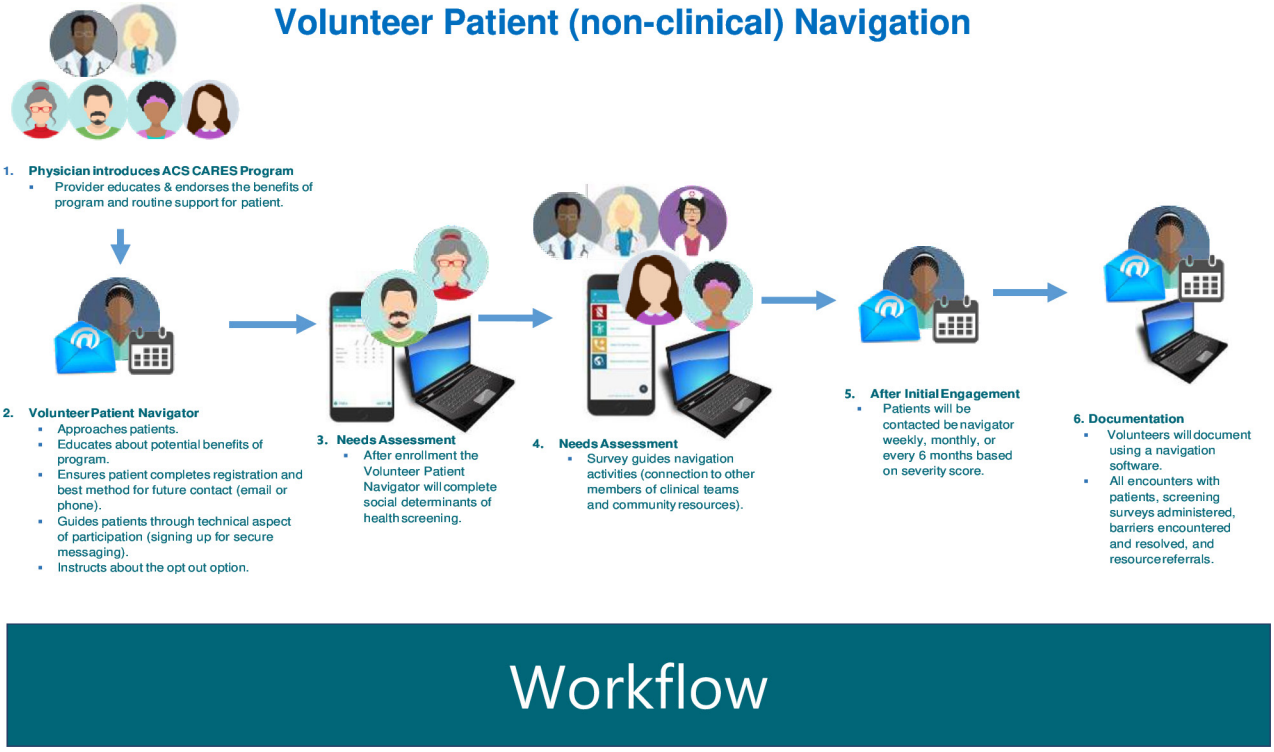


**Figure 1** Conceptual model for improvement in outcomes from the use of remote symptom monitoring. ACS CARES, American Cancer Society Community Access to Resources, Education, and Support.

piloted in three separate and highly diverse ambulatory clinics: (1) Adult Neuro-Oncology, (2) Pediatric Bone and Soft Tissue Sarcoma and (3) Pediatric Leukemia and Hematopoietic Stem Cell Transplant. The latter two clinics see a roughly even split between Medicaid (MediCal) and Preferred Provider Organization (PPO) insurance with roughly 20%–30% of families with Spanish as their preferred language. The MUSC is the only NCI-designated cancer centre in South Carolina. They have a strong focus on the care of underserved patients and those in rural areas, serving as 1 of only 14 NCI Minority/Underserved Community Oncology Research Program sites and have a strong existing nurse navigation programme. The ACS CARES programme will be piloted at MUSC in the head and neck radiation oncology, genitourinary medical oncology and thoracic surgery clinics.

## Navigation components

### Volunteer non-clinical navigation

Navigation will be implemented as standard of care for patients receiving care with a participating oncologist offering the intervention, thus no consent will be required. The navigation process and activities are shown in figure 1.

The oncologist or other healthcare team member will introduce the programme to new patients as an approach for routine patient support. ACS CARES volunteers then approach new patients in-person to introduce the programme, discuss potential benefits and capture the best method for future contact (encrypted messaging vs phone). The volunteers guide the patients through any technical aspects of participation, such as signing up for secure messaging. Patients will be allowed to opt out of participation. After enrolment, the volunteer will complete a social determinants of health screen (table 2), which will guide navigation activities including connection to other members of the clinical team, health system resources and community resources. Initial contact will be predominantly in person, but phone contact will be permitted. After the initial engagement, patients will be contacted by the volunteer weekly, monthly or every 6 months based on a severity score calculated based on number of barriers and type of barrier. Volunteers will document using a navigation software all encounters with patients, screening surveys administered, barriers encountered and resolved, and resource referrals. Clinical teams have access to dashboards of activities completed both for individual patients and in aggregate.

### Staff training

We offer a two-part training curriculum for volunteers. The initial training is self-paced, online and includes the following modules: privacy training, IT security awareness for volunteers, introduction to phishing, IT security and acceptable use, ACS programmes and services, ACS CARES programme overview, introduction to patient navigation, history of navigation, cancer 101, identifying and addressing needs across the cancer continuum, financial basics, health equity, clinic student volunteer role expectations, introduction to cancer caregiving, introduction to childhood and AYA cancer. On completion of this online training, an in-person training is held at each site

Table 2 Survey instruments

| Domain | Instrument or source | Number of questions | Time points | Constituent |
|---|---|---|---|---|
| Demographic characteristics | Study-specific questionnaire | 8 | Baseline and 6 months | Patient |
| Social determinants of health | NCCN Distress Thermometer[19] | 1 | | |
| Unmet needs | Supportive Care Needs Survey (SCNS-SF34)[20] | 22 | | |
| Patient-provider communication | Patient-Centered Communication Scale[21] | 7 | | |
| Clinical trials knowledge | Clinical Trials Knowledge[22] | 7 | | |
| Patient satisfaction | Satisfaction Measure[23] | 17 | | |
| Patient activation | Patient Activation Measure[24] | 13 | | |
| Financial toxicity | FACIT-COST[26] | 11 | | |
| Quality of life | PROMIS Global Short Form[27] | 10 | | |
| Volunteer satisfaction | Volunteer Satisfaction Index[18] | 30 | 1 year | Volunteer |

FACIT-COST, Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity; NCCN, National Comprehensive Cancer Network; PROMIS, Patient-Reported Outcomes Measurement Information System.

that includes a tour of the clinic space, appropriate documentation practices, role-playing practice scenarios and integration of all aspects of the role. Finally, the volunteers learn and practice documentation. The lead oncologist and administrators are invited to training and are responsible for educating other oncologists, nurses, social workers and clinical staff about the programme. Materials are provided to support this effort, including a *Clinic Flow Sheet* describing volunteer responsibilities and key opportunities for clinic integration, and an *In and Out of Scope Document* detailing potential opportunities for volunteer engagement. The opportunity to customise clinic integration and volunteer engagement to the needs and preferences of the clinical team is offered at this time. The number of volunteers completing each training component is recorded. A super-user from ACS completes weekly check-ins and continuing education with the volunteer teams and the ACS CARES team provides support on an ongoing basis, including bi-weekly meetings with the pilot site teams.

## Research components on implementation

### Implementation frameworks

The Updated Consolidated Framework for Implementation Research (CFIR) by Damschroder and colleagues is optimal to guide the evaluation of the ACS CARES programme. The updated CFIR focuses on key domains: innovation, outer setting, inner setting, individuals, implementation process and outcomes.[15 16] Proctor's Implementation Outcome Framework[17] will be used in the assessment of implementation outcomes and inform future implementation effort expectations.

#### *Sampling and recruitment*

This study will include three groups of participants: (1) site coordinators, (2) volunteer navigators and (3) patients. The site coordinators from each site will function as administrative leads. For volunteers, we will include all volunteers participating in the programme. There are no exclusion criteria for volunteers. The patient group will be identified through a review of electronic records and composed of all adults receiving their treatment from a participating oncologist (regardless of whether they participate in the navigation programme) in 2022–2024. Patients can receive concurrent treatments (eg, radiation, surgery). Patients of with age 18 years or older, races and ethnicities, and insurance types will be included for the duration of their treatment. Patients who are seen for a second opinion will be excluded. Intervention patients will include all patients who are enrolled in ACS CARES. For the control population, we will include historical controls who are seen in the year prior to ACS CARES implementation by the providers participating in ACS CARES.

## EVALUATION

### Component 1: implementation outcomes

#### Intervention context

##### *Data collection*

Field notes documentation from discussions with administrative leads will be captured throughout the programme to provide implementation context. This will include the number of clinical navigators, professional patient navigators and social workers at each participating site, the number of clinical providers and clinics engaging with ACS CARES volunteers at each site, barriers and facilitators identified in implementing the pilot programme, the date and details of any changes, team staffing or organisation, institutional policy changes and national policy changes that we anticipate will impact the ACS CARES programme. For volunteers, training materials and logs will be captured and reviewed on an ongoing basis to evaluate the percentage of trainees completing each component of the training.

### Analysis

A Consolidated Standards of Reporting Trials diagram for single-arm studies without randomisation will be created. Descriptive statistics will be included for a number of providers and training components. Other information within this aim will be used to frame and interpret other analyses detailed below.

### Process measures

Implementation outcomes related to the process are based on Proctor's Implementation Framework[17] and will be assessed using secondary data from the ACS CARES navigation software platform. Training will be measured with the following metrics: student completion or volunteer requirements, number of trainings conducted (initial and continuing education) and time to complete onboarding. Patient service penetration will be evaluated using the following outcomes: patients/caregivers approached for ACS CARES; patients/caregivers who decline and reason for refusal; patients/caregivers supported by ACS CARES; patients/caregivers who received psychosocial distress screening; patients/caregivers who received social determinants of health (SDOH) screening; volunteer follow-ups conducted; in-person visits conducted; volunteer shifts completed and direct referrals received from health system team members.

### Analysis

We will first descriptively summarise baseline health system characteristics, participant demographics and study outcomes. We will examine differences in patient characteristics between those who participate and those who do not use bivariate measures of association (eg, Cohen's d, Cramer's V). For patient outcomes, the site and navigation team will be treated as fixed effects when needed, as all navigation teams will be included. The primary analysis will be conducted using logistic regression models to estimate the service penetration proportions of interest throughout the project. Model-predicted means and inverse-link transformations will be used to estimate the proportions of interests and respective CIs. Secondary analysis for patient outcomes will be conducted using logistic regression models to evaluate the association between patient characteristics and penetration outcomes. Patient characteristics will include age, sex, race and ethnicity, rurality (estimated using rural–urban commuting area (RUCA) codes) and socioeconomic disadvantage status (estimated using the Area Deprivation Index). For clinician metrics, generalised linear mixed models with random effects for the clinician team will be used to estimate the monthly response to alerts and time to response. A false discovery rate (FDR) approach[18] will be used to correct for multiple inferences when appropriate (10% FDR).

### Sample size considerations

The sample size for this portion of the study will be based on the volume of new patients seen by participating oncologists; thus, no formal sample size calculation is needed.

## Component 2: health system and utilisation outcomes

### Design

This component will include secondary, descriptive analysis of existing data capture both within the electronic medical record and electronic navigation platform. No active recruitment will occur as part of this study component. Pilot sites will abstract data from the electronic medical record (EMR) and provide ACS with a limited dataset for analysis from two time periods.

### Populations of interest

Patients (1) age ≥18, (2) with an ICD-10 diagnosis codes for an eligible cancer at participating institution. Each site will define their pilot population based on the oncologists participating in the pilot programme. Sites will differentiate between new eligible patients and all eligible patients. The baseline patient population will include patients seen by participating oncologists from 1 January 2022 to 31 December 2022. The intervention patient population will include patients seen from 1 September 2023 to 31 August 2024. The volunteer population will include all volunteers participating in the programme.

### Data abstraction

The following patient data from the EMR will be abstracted: age, sex, race and ethnicity, insurance status, home address (to determine rurality), cancer type, cancer stage, diagnosis date, date of new patient appointment, treatment types (surgery, chemotherapy, radiation therapy, targeted therapy, immunotherapy, stem cell or bone marrow transplant, hormone therapy), total clinic appointments, # clinic appts missed/cancelled, total infusion appointments, # infusion appointments missed/cancelled, total radiation treatment appts, # radiation treatment appointments missed/cancelled, enrolled in a clinical trial (yes/no), start date of clinical trial participation, emergency room (ER) visits, hospitalisations, ICU admissions, total cost of care. Sites will use home addresses to characterise patients as living in urban or rural residences (RUCA codes) and in areas of high or low area deprivation as a measure of socioeconomic disadvantage (Area Deprivation Index scores).[19] Chart review will be completed as needed to minimise missing data. Navigation data will be abstracted from the NurseNav system (navigation platform technology). From this system, data will be abstracted monthly and will include the number of patients/caregivers approached, enrolled and declined ACS CARES participation; the number of patients/caregivers supported by ACS CARES who received psychosocial distress and social determinants of health screening; the number of follow-ups conducted (in person and remote); the number of shifts completed per volunteer; the number of referrals to the programme received.

### Outcomes

Access will be defined by the following metrics for the above populations: (1) time to treatment=the time from initial appointment with the clinical team to first treatment; (2) time to volunteer navigation=time from new patient appointment with the clinical team to first navigation contact; (3) time from volunteer navigation to first treatment=time from first volunteer navigator appointment to first treatment; (4) receipt of clinical trial during study period. This will be captured overall and by type of treatment (surgery, medical therapy, radiation). Healthcare utilisation will be defined by the per cent of patients with each type of event (ED, hospitalisation, ICU admission, no show to clinic appointment). Each of the event types will be described as events per month. The average total cost of care will also be calculated monthly. All outcomes will be assessed for all patients (navigated, not navigated, both) and for new patients (navigated, not navigated, both) from June 2023 to September 2024 from the target population.

### Statistical analysis

We will summarise sociodemographic characteristics, adherence and utilisation measures by navigated/not navigated with means and SD for continuous variables, counts and proportions for categorical variables and compare with t tests and $\chi^2$ tests. We will use multivariable logistic regression or multivariable generalised linear regression with a beta distribution and logit link, depending on the outcome for each analysis. Site and volunteer will be treated as fixed effects when needed, and we will consider two-way interaction terms for all covariates.

### Power and sample size considerations

The three participating sites will select the clinics for implementing ACS CARES; thus, power and sample size will be dependent on the enrolment at the sites and not predetermined. We anticipate each site to enrol at least 200 patients, for a minimum of 600 patients across sites.

## Component 3: volunteer satisfaction

### Population

Volunteers participating in ACS CARES at the three pilot sites. We will be working closely with the volunteers implementing the ACS CARES programme throughout the pilot project. Each of these volunteers committed to at least 1 year of participation as part of their selection for participation in the project.

### Data collection

For evaluation of volunteer experience, all volunteers will be asked to participate in a 15 min, 30-question Volunteer Satisfaction Index survey[20] in May 2024 assessing perspectives on the programme. Participation will have no impact on the ability to continue volunteering for the programme.

### Outcomes

Volunteer satisfaction will be measured by the Volunteer Satisfaction Index,[20] which consists of 26 items in four subscales for organisational support, participation efficacy, empowerment and group integration. Item responses are given using a 7-point Likert scale ranging from strongly dissatisfied to strongly satisfied. It has previously demonstrated satisfactory alpha coefficients for all subscales, ranging from 0.75 to 0.91.

### Sample size considerations

While we expect high participation (>75%) from the volunteers based on prior volunteer engagement, we note that the sample size for volunteers will be small (estimated 5–10 per site) due to the limited volunteer pool and thus will be hypothesis-generating for future studies.

## Component 4: patient-reported outcomes

Design: this component will include two analysis: (1) secondary data analysis of data from the navigation software to evaluate distress, barriers to care, resources used and SDOH and (2) cross-sectional patient surveys to assess patient experience within the health system.

### Distress and social determinant of health analysis

#### *Population*

For part 1 (secondary analysis), the intervention patient population will be as described above for the secondary analysis component.

#### *Data abstraction*

The following data will be abstracted from the navigation platform: distress score (0–10) based on the NCCN distress thermometer[21]; information needs and SDOH barriers endorsed based on the NCCN problem list; information needs identified, barriers identified, information/resources provided to patient/caregivers (through ACS or external).

#### *Statistical analysis*

Distress scores and problem lists will also be evaluated longitudinally to capture trajectories and change over time. We will summarise standard navigation metrics, including the number of patients educated on clinical trials by an ACS CARES volunteer, the number of patients referred to clinical trials staff by an ACS CARES volunteer, and the top three barriers to care identified by an ACS CARES volunteer.

#### *Power and sample size considerations*

The three participating sites will select the clinics for implementing ACS CARES; thus, the power and sample size will be determined once clinics have been selected.

### Cross-sectional survey

#### *Population and data collection*

Patients and caregivers of participating oncologists will be invited to participate in a 30 min, 96-question survey to assess satisfaction with the programme, unmet needs,

clinical trials knowledge, patient activation, financial toxicity and quality of life. Each site staff or volunteers will provide an informational sheet on the study to potential participants on the opportunity to participate in an ACS-led survey by mail, e-mail, portal message or phone call. If interested, they will use an electronic link to an online survey fielded in REDCap. For those unable to complete electronically, the option to complete the survey by phone will be available. Participants will be able to opt out of the survey at any time. Participants will receive a US$20 electronic gift card for their participation.

### Outcomes

*Unmet needs* will be measured using the SCNS-SF34[22] scale, which includes 34 items mapped to five domains, psychological, health system, physical and daily living, patient care and support, and sexuality. For each item, respondents are asked to indicate their level of need for help over the last month as a result of having cancer, using the following response options: (1) no need—not applicable; (2) no need—satisfied; (3) some need—low need for help; (4) some need—moderate need for help; (5) some need—high need for help. The SCNS-SF34 takes approximately 10 min to complete. *Patient–provider communication* will be assessed using the 7-item Patient-Centered Communication Scale.[23] The PCC scale uses a Likert-like four-point scale: always (1), usually (2), sometimes (3) and never (4). Scale scores are created by reverse-scoring all items, summing all scores taking the average, and doing a linear transformation to change the range from 0 to 100 with higher scores meaning better communication with one's provider. *Clinical trials knowledge* will be measured using the 7-item questionnaire developed by Ellis and colleagues to ascertain knowledge about clinical trials.[24] *Patient satisfaction* will be measured using a satisfaction measure developed specifically for navigation programmes, which includes access to care, coordination of care, patient–provider communication, quality of care and patient engagement domains.[25] *Patient activation* will be measured using the Patient Activation Measure (PAM).[26] PAM scores range from 0 to 100 and fall under four levels of activation. Level 1 (a score of 0.0–47.0) implies low activation, or not believing activation is important. Level 2 (47.1–55.1) indicates lack of knowledge and skills to take action. Level 3 (55.2–72.4) implies beginning to take action, and level 4 (72.5–100) is the highest level of activation and indicates a patient is proactive in managing their condition.[27]

*Financial toxicity* will be measured using a response to the Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity (FACIT-COST) measure, which is an 11-item measure of financial toxicity.[28] *Quality of life* will be measured using the Patient-Reported Outcomes Measurement Information System (PROMIS) Global measure, which is a 10-item questionnaire that measures physical health, physical functioning, general mental health, emotional distress, satisfaction with social activities and relationships, ability to carry our usual social activities and roles, pain, fatigue and overall quality of life.[29]

### Statistical analysis

We will summarise sociodemographic characteristics and patient-reported outcomes (PROs) by navigated/not navigated with means and SD for continuous variables, counts and proportions for categorical variables, and compare with t-tests and $\chi^2$ tests. We will use multivariable logistic regression or multivariable generalised linear regression depending on the outcome of each analysis. Site and volunteer will be treated as fixed effects when needed, and we will consider two-way interaction terms for all covariates.

### Power and sample size considerations

Only patients of participating physicians will be included; thus, the sample size will be limited to this population and a formal power calculation will not be completed.

### Synthesis into implementation blueprint

Within the implementation of ACS CARES, we will develop a formal implementation blueprint,[30 31] which will include processes for volunteer navigation, expected outcomes, information on the context and training. This blueprint will provide guidance to future sites interested in implementing ACS CARES. This will not include any patient-specific or provider-specific data.

## DISCUSSION

There is increasing interest to build strong navigation programmes, which is likely to be enhanced by the proposed 2024 Medicare rule to provide reimbursement for navigation services.[32] In this policy context, there will be substantial opportunities to build strong teams to support patients. The addition of student volunteers to navigation provides an interesting synergy where students may gain experience while accomplishing lower-skill-level activities. This approach may also help minimise burnout among nurses and other members of the healthcare team, by reducing clerical and other activities that do not require advanced training to accomplish. Evaluation of such programmes will be critical both to ensuring the success of ACS CARES but also may provide a frame for how to guide implementation of inclusion of volunteers in other aspect of medical care.

This project also emphasises health equity both in the inherent tenants of navigation and the consideration of potentially vulnerable populations within the analysis plan. Analysis of key subsets by race and rurality will provide key data on how volunteers may impact these particular populations and lead to further advancement in how to ensure equitable care delivery. This is particularly important because the use of student volunteers could result in volunteers who are less likely to be of the communities served than community health worker models and thus recruitment strategies will be implemented to support diverse participation. Such opportunities may be particularly appealing to volunteers

from marginalised communities and provide a mechanism to support their growth as future social workers, nurses and physicians that reflect the communities existing in the USA. Future efforts will be aimed to linking historically black colleges and universities and Hispanic-Serving Institutions to this effort, specifically to achieve this mission.

A limitation of this study is that there may be differences between those who participate in ACS CARES and those who do not participate. We are limiting the control population to the same providers participating in the project, which will minimise variability in disease characteristics, and we control for key patient and clinical characteristics, there may be unmeasured factors that influence both willingness to participate and downstream outcomes. Another limitation is the potential for missing data. This is a pragmatic study that will leverage existing health system data and thus some data elements (eg, staging) may be absent of incomplete. Implementation was conducted within specific clinics, where physician champions were present, which may result in improved implementation outcomes compared with a broader roll-out with less engaged providers. Furthermore, a formal power analysis is not included because the patient population was dependent on participating providers, thus effectiveness outcomes will be hypothesis-generating and will require further testing in future, appropriately powered studies. We will leverage statistical methods (imputation, sensitivity analysis) to address these concerns. At the same time, we note the pilot nature of this study and focus on early implementation and feasibility that is less likely to be impacted by this missing data. We anticipate additional data collection in future years that will be able to bolster this early analysis. Another potential limitation is that this study only involves three sites presently. While there are plans to expand further, this initial analysis is limited by the characteristics of the participating sites. While these are geographically diverse institutions, they may have different processes of care delivery and existing navigation resources than other sites. For example, all three are academic comprehensive cancer centres, which may have greater resourcing than community oncology practices. We will monitor and document current infrastructure and utilise this knowledge as a foundation for future expansion efforts. We also acknowledge as a limitation the lack of formal collection of provider and system outcomes, which will be evaluated in a future study. Ultimately, we anticipate that this study will provide the needed implementation blueprint for the rapid growth of this model through the ACS network of partners. Future studies will consider how this model is scaled up within the existing institutions and scaled out to new institutions.

## ETHICS AND DISSEMINATION

### Ethics approval and consent to participate

This study was approved by the University of Morehouse School of Medicine Social and Behavioral (IRB), which served as the IRB for the record for this project (IRB-2025819–2). No consent required for this study protocol. Future research will disseminate findings on the scalability of this model within current institutions and its adaptability for implementation in new institutions.

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**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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