Cover Page

Official Title: Evaluating the implementation and impact of standard-of-care delivered oncology financial navigation

NCT Number: Pending

Date of document: February 28, 2025

Study/Protocol Title: Evaluating the implementation and impact of standard-of-care delivered oncology financial navigation

Table of Contents:

Primary Investigator:

Courtney P. Williams, DrPH
Assistant Professor
Division of Preventive Medicine, University of Alabama at Birmingham
1720 2nd Avenue South, MT 639, Birmingham, AL 35294
Office: (205) 975-0462
courtneywilliams@uabmc.edu

Mentors:

Gabrielle B. Rocque, MD, MSPH
Associate Professor, Division of Hematology & Oncology, UAB Department of Medicine
grocque@uabmc.edu

Lisa Zubkoff, PhD
Associate Professor, Division of Preventive Medicine, UAB Department of Medicine
lisazubkoff@uabmc.edu

Janet Turan, PhD, MPH
Professor, Department of Health Policy and Organization, UAB School of Public Health
jmturan@uab.edu

Collaborators:

Maria Pisu, PhD
Professor, Division of Preventive Medicine, UAB Department of Medicine
mpisu@uabmc.edu

Andres Azuero, PhD, MBA
Professor, Department of Family, Community, & Health Systems, UAB School of Nursing
andreo@uab.edu

Statisticians:

Luqin Deng, PhD
Scientist III, Division of Preventive Medicine, UAB Department of Medicine
luqindeng@uabmc.edu

Sandra Olisakwe, MSPH
Clinical Data Analyst, Division of Hematology & Oncology, UAB Department of Medicine
scolisakwe@uabmc.edu

1. **Background and Significance**
    a. **Financial hardship, defined as out-of-pocket costs and their accompanying financial distress, is a significant issue for individuals with cancer.** Financial hardship often results in adverse (1) material outcomes, such as trading off spending on food or housing to pay for medical bills; (2) behavioral outcomes, by delaying or foregoing medical care due to costs; and (3) psychological outcomes, through increased distress and decreased quality of life.[1] Additionally, patients who are minoritized, rural residents, underinsured, or socioeconomically disadvantaged are at inequitably higher risk for cancer-related financial hardship.[2-13] *Addressing high out-of-pocket costs and financial distress is imperative for ensuring favorable outcomes for individuals with cancer.*

    b. **Financial hardship screening data is routinely collected and reveals high levels of financial hardship in patients receiving oncologic care at the University of Alabama at Birmingham (UAB).** Financial hardship screening measures were incorporated into an electronic medical record (EMR)-integrated, standard-of-care, treatment planning survey implemented at UAB as a Center for Medicare and Medicaid Innovation's (CMMI) Oncology Care Model practice transformation activity.[14-16] Screening has been conducted since 2020 either electronically pre-clinic visit or by a trained lay navigator in-person at routine clinic visits or over the phone. Financial hardship screening is comprised of (1) the validated 11-item COmprehensive Score for financial Toxicity (COST) tool to capture cancer-related financial distress,[17, 18] and (2) ten individual domains of financial difficulty, including trouble paying for basic needs, utilities, transportation or lodging for treatment, medications, medical supplies, upfront medical payments, insurance or medical bills, child or eldercare, and employment or disability issues. Of ~3,000 UAB oncology patients screened through May 2023, 34% were experiencing financial distress. Reported distress also differed by race, with 49% of Black patients screening positive for financial distress compared to 30% of White patients. Differences in types of financial difficulties were seen comparing Black and White patients, including 44% vs. 23% reporting difficulty with upfront medical payments and 28% vs. 12% reporting financial difficulties with transportation for care, respectively.[19] *Though high levels of financial hardship exist, how to routinely address patient-reported financial hardship in clinical settings using evidence-delivered interventions is unknown.*

    c. **Oncology financial navigators, a new health care team member, could aid in reducing patient-reported financial hardship.** Oncology financial navigation is an evidence-based intervention which helps patients prepare for out-of-pocket treatment costs, optimize health insurance, and access financial resources to reduce cancer-related financial hardship (see Section C for a detailed description of financial navigation components).[20] Results from research-based, pilot, oncology financial navigation studies indicated this intervention was feasible and showed high patient acceptability and appropriateness.[21] Additionally, research-based evaluations have shown oncology financial navigation interventions result in decreased patient financial hardship, financial anxiety, and individual annual savings of >$30,000.[22-26] Though research-based integration of oncology financial navigators has been proven beneficial for patients in controlled settings, little is known about how to implement oncology financial navigation into routinely-delivered oncologic care, especially for systems serving patients experiencing large inequities in financial hardship. Thus, e*valuation of oncology financial navigation integration into real-world clinical care, especially for highly diverse and under-resourced patient populations, is needed to ensure equitable implementation.*

2. **Study Objectives**

Guided by the RE-AIM Extension for Equitable Sustainability framework,[27] we will use a series of implementation and effectiveness aims to evaluate equitable implementation of oncology financial navigation into routine cancer care delivery. *This study will build upon my existing skills* in quantitative research methods, which has provided foundational work to better understand cancer-related financial hardship, and allow me to develop new skills in implementation science, pragmatic trials, and qualitative methods to address financial hardship. We *hypothesize* the proposed assessment will identify potential areas to improve implementation of oncology financial navigation, which will result in better financial and clinical outcomes for patients with cancer. We propose a pragmatic, hybrid effectiveness-implementation study[28] to assess outcomes of oncology financial navigation delivered as

routine cancer care and collect information on strategies to address implementation barriers. Outcomes will be assessed overall and for inequities by race, residence, and insurance status using the following *specific aims*:

Aim 1. Track oncology financial navigation implementation strategies and their effect on implementation outcomes. We will track oncology financial navigation implementation strategies (using the Longitudinal Implementation Strategy Tracking System[29]) and effect on outcomes, including reach (patients who receive financial navigation), adoption (positive financial hardship screens addressed), implementation fidelity (proportions of financial navigation core components completed), and maintenance (≥3 months of ≥60% of positive financial hardship screens addressed with ≥60% of core components completed). *Training goal:* Dr. Lisa Zubkoff will provide mentorship in *implementation science frameworks, strategies, outcomes.*

Aim 2. Evaluate oncology financial navigation effectiveness. For patients receiving oncology financial navigation compared to historical controls ("usual care"), we will use routinely collected, patient-reported data to evaluate change in patient-reported measures of financial distress (COmprehensive Score for financial Toxicity[17]), financial difficulties (10 individual domains, such as transportation to care or prescriptions), quality of life (PROMIS v1.1 Global Health[30]), and psychological distress (National Comprehensive Cancer Network Distress Thermometer[31]). *Training goal:* Dr. Gabrielle Rocque will provide mentorship in *pragmatic trial conduct and design.*

Aim 3. Assess how implementation strategies were utilized to overcome barriers to oncology financial navigation. Using qualitative interviews, we will assess how oncology financial navigation implementation strategies were leveraged to address implementation barriers identified from patient (N=20), provider (N=10), and health system (N=10) perspectives. *Training goal:* Dr. Janet Turan will provide mentorship in *qualitative methodologies*.

3. Design Considerations and Preliminary Studies

a. **Design Considerations.** This evaluation of oncology financial navigation implementation outcomes and effectiveness is intentionally designed to be a pragmatic evaluation of largely secondary data. UAB rolled out routine financial hardship screening in 2020. To respond to the high prevalence of financial hardship identified by screening in our patient population, UAB is currently prioritizing the hiring and integration of oncology financial navigators into clinical teams, independent of this grant mechanism. We will leverage this screening data, which is available in the EMR (Aims 1&2), that have been collected since 2020 (Aim 2), and which will trigger oncology financial navigation (Aim 1), to achieve our aims. Thus, we will not conduct a formal randomized control trial or select outcomes not already included in our standard-of-care screening data. The pragmatic nature of this study, as well as the >3,000 patients with financial hardship screening data already collected, greatly strengthens our study.

b. **Preliminary studies.**

i. **Successful navigation program supporting cancer patients utilized implementation strategies.** Drs. Rocque (*primary mentor*), Pisu (*collaborator*), and Williams (*PI)* implemented and evaluated a lay navigation program across 12 southeastern cancer centers, including UAB.[32, 33] Over a 3-year period, this program employed non-clinical lay navigators to provide support to >10,000 cancer patients.[34] Lay navigators used routine distress screenings to identify barriers to care and empower patients to overcome these barriers.[35] Lay navigators were able to address 92% of patient concerns, and 90% of patients would recommend the program to others.[34] This project highlights the team's experience working with navigators and evaluating the impact of novel delivery approaches on patient outcomes.

ii. **Assessment of real-world data for program evaluation.** Drs. Rocque (*primary mentor*), Azuero (*collaborator*), and Williams (*PI*) conducted a pragmatic study of real-world implementation of remote symptom monitoring using patient-reported outcomes at UAB. The evaluation integrated EMR, registry, and patient-reported outcome data in >2,000 patients to demonstrate implementation success. Preliminary data shows a 20%

reduction in hospitalizations at 6 months (HR 0.8, 95% CI 0.6-1.1). To achieve these results, 39 distinct implementation strategies were utilized in initial implementation and scale-up. Strategies were linked with qualitative interview data to describe utility of implementation strategies using LISTS (*preliminary data presented at 2023 Academy Health Annual Meeting for Dissemination and Implementation Science*). This project demonstrates capacity to conduct pragmatic implementation evaluation of standard-of-care interventions within large patient populations.

4. Investigation Plan and Study Procedures

a. Aim 1. Track oncology financial navigation implementation strategies and their effect on implementation outcomes.

i. Objectives: (1) Track oncology financial navigation implementation strategies and (2) their effect on implementation outcomes overall and by race, residence, and insurance status.

ii. Approach: Use secondary data routinely collected in the EMR and EMR-embedded navigation software to evaluate implementation strategies and outcomes over time.

iii. Sampling: *Oncology financial navigation is a high priority for the UAB Cancer Service Line and will be implemented as standard of care, independent of this study.* Oncology financial navigators will approach all patients receiving systemic cancer treatment (chemotherapy, immunotherapy, targeted therapy). No consent will be required as this will be a standard-of-care intervention offered to all patients. The oncology financial navigator will review the patient-reported financial distress and difficulty data and if necessary, triage to appropriate care team members (psycho-oncology, lay navigation, social work). Dr. Williams (*PI*) has been working closely with the Medical Director of Quality for the UAB Cancer Service Line (*Dr. Rocque; primary mentor*), Director of Program Planning & Performance Improvement for the UAB Cancer Service Line, and Manager of UAB Ambulatory Oncology Social Work & Lay Navigation to develop the oncology financial navigator program, including evidence-based[20] core components specific for the UAB oncology financial navigators. These include (1) individualized estimations of out-of-pocket costs based on each patient's health insurance plan, (2) patient education on insurance, billing, and employment, and (3) patient assistance with copay assistance or charity care requests. As oncology financial navigation will be implemented as standard of care, implementation outcomes will be evaluated for (1) all patients with cancer seen at the UAB Medical Oncology clinic, and (2) UAB oncology financial navigators.

iv. Training: In addition to standard onboarding from the UAB Health System, Dr. Williams (*PI*) and key implementation team members (including Dr. Pisu [*collaborator*]) will conduct training specific for oncology financial navigators. Training materials will include modules from the Association of Community Cancer Centers Financial Advocacy Bootcamp, George Washington University's Oncology Financial Navigation Training, and Triage Cancer's Legal and Financial Navigation Program.

v. Data collection: Implementation outcome data will be abstracted from the EMR and HealtheCare, the EMR-embedded navigation software. Data uncaptured by the EMR and navigation software will be captured during implementation meetings with the implementation team and oncology financial navigators.

vi. Implementation strategies: Implementation strategies (**Table 1**) were identified *a priori* by the implementation team. During implementation, Dr. Williams (*PI*) will use the LISTS[36] tool to track implementation strategy utilization using the Expert Recommendations for Implementing Change (ERIC[37]) compilation. Implementation strategies will be assessed quarterly through formal tracking using the LISTS REDCap[38] tool and reviewed with Dr. Zubkoff (*co-mentor*) and the larger mentorship team (GR, JT).

Table 1. Potential implementation barriers, selected implementation strategies, planned actions, and potential interview prompts.

Barrier	Implementation strategy	Action	Aim 3 interview prompts
Clinical staff unaware of financial navigators	Identify and prepare champions	Implementation team trains staff champions	What have you done to build buy-in for the financial navigation program?
Financial navigators are untrained	Conduct ongoing training	Implementation team trains all financial navigators	What were the strengths and weaknesses of the financial navigation training?

Resources for financial navigators are uncharacterized	Develop resource sharing agreements	Implementation team creates baseline set of resources	What resources were needed to address patient financial needs?
Patient financial needs historically addressed by social workers	Revise professional roles	Clinical team will introduce financial navigator to patient	What was the level of patient awareness regarding financial navigation services?
Implementation strategies not addressing contextual needs	Purposely reexamine the implementation	Implementation team adjusts implementation strategies	How did adjustment of implementation strategies respond to financial navigation program needs?

vii. Implementation outcomes: Implementation outcomes (**Table 2**) will be anchored in the RE-AIM Extension for Equitable Sustainability.[27] All patient outcomes will be assessed both for the overall population of interest, and for inequities by patient subgroups, including race (white, Black/person of color), residence (rural, urban), and insurance status (private, Medicare, Medicaid, other, uninsured). Implementation reach, adoption, fidelity, and adaptation will be captured monthly, while implementation maintenance will be captured annually.

Table 2. Project aim outcomes, concepts, units of assessment, evaluation metrics, and evaluation timing.

Aim	Outcome*	Concept	Unit of assessment	Evaluation metrics	Evaluation timing
1	Utilization of implementation strategies	Expert Recommendations for Implementing Change (ERIC) implementation strategies[37]	Patients, providers, health system	Longitudinal Implementation Strategy Tracking System (LISTS)[29]	Quarterly
	Implementation outcomes	Reach	Patients	Proportion who receive OFN; Characteristics of participants vs. non-participants	Monthly
		Adoption	Oncology Financial Navigators	Proportion who participate in training; Average positive financial hardship screens addressed; Time to response; Type of response to positive screens	
		Implementation fidelity and adaptation	Oncology Financial Navigators	Proportions of core components completed; Consistency of OFN-delivered core components across patient subgroups; Adaptations to OFN; Reasons for adaptations	
		Maintenance	System	Proportion of OFN with ≥3 months of ≥60% of positive financial hardship screens addressed with ≥60% of OFN core components completed	Annually
2	Effectiveness outcomes	Financial distress	Patients	COmprehensive Score for financial Toxicity[17]	Six-month change scores
		Financial difficulties		Proportion reporting ten individual domains of financial difficulty	
		Quality of life		PROMIS v1.1 Global Health[30]	
		Psychological distress		National Comprehensive Cancer Network Distress Thermometer[31]	
3	Patient, provider, and health system perspectives	Implementation barriers addressed via implementation strategies	Patients	Patient subgroups unreached by OFN; Effectiveness of OFN-delivered services for certain patient subgroups	Annually
			Providers and health system	Consistency of OFN-delivered core components; OFN capacity and resources	

*Outcomes will be assessed overall and by patient race, residence, and insurance status. OFN=Oncology Financial Navigation

b. **Aim 2. Evaluate oncology financial navigation effectiveness.**

i. Objectives: To evaluate the effectiveness of oncology financial navigation overall and for inequities by race, residence, and insurance status using the change in patient-reported financial distress, financial difficulties, quality of life, and psychological distress for patients receiving oncology financial navigation compared to historical controls ("usual care").

ii. Approach: To use existing, routinely collected, patient-reported data to compare outcomes from patients receiving oncology financial navigation to matched historical controls.

iii. Sampling: This will be a secondary data analysis of patient-reported data routinely collected since 2020 for patients with cancer seen at the UAB Medical Oncology clinic. All patients with data will be included in the analysis, as this is an evaluation of oncology financial navigation integration into real-world clinical teams. Therefore, due to a lack of comparable controls during the oncology financial navigation intervention, we will use *historical* controls matched by sociodemographic and cancer characteristics for comparison. To minimize confounding, we will use data reported by UAB Medical Oncology patients from the previous 3 years. Patient data and sources are shown in **Table 3**.

Table 3. Patient data and sources.

Sources	Patient data
Electronic medical record-abstracted data	Sociodemographics (age, race, sex, home address [to calculate socioeconomic proxies: Area Deprivation Index,[39] Social Vulnerability Index[40]], insurance status)
	Clinical characteristics (cancer type, cancer stage, cancer diagnosis date, comorbidities)
Patient-reported data	Financial distress (COmprehensive Score for financial Toxicity[17])
	Financial difficulties (trouble paying for basic needs, utilities, transportation or lodging for treatment, medications, medical supplies, upfront medical payments, insurance or medical bills, child or eldercare, and employment or disability issues)
	Quality of life (PROMIS v1.1 Global Health[30])
	Psychological distress (National Comprehensive Cancer Network Distress Thermometer[31])

c. **Aim 3. Assess how implementation strategies were utilized to overcome barriers to oncology financial navigation.**
   i. Objectives: Assess perceptions of how selected implementation strategies were used to address implementation barriers from the patient, provider, and health system perspectives.
   ii. Approach: Conduct semi-structured qualitative interviews from diverse perspectives to assess implementation barriers and adequacy of strategies to overcome barriers.
   iii. Sampling: We will identify individuals to participate in 30-60 minute-long interviews. Patient participants (N=20) will be purposively selected using maximum variation sampling to ensure representation of differing races, residences, and insurance statuses. Provider (oncology financial navigators, social workers, nurse managers, oncologists; N=10) and health system (billing specialists, cancer service line leadership; N=10) participants will be selected using purposive sampling of individuals involved with the oncology financial navigation program. A $50 participation incentive will be provided.

5. Data Analysis

a. **Aim 1. Track oncology financial navigation implementation strategies and their effect on implementation outcomes.**
   i. Statistical analysis: Descriptive statistics will be calculated for oncology financial navigator sociodemographics, patient sociodemographics and clinical characteristics, and implementation outcomes. Oncology financial navigation will be delivered as standard of care. However, patient sociodemographics who decline oncology financial navigation will still be collected and compared to examine the implementation outcome of reach using bivariate measures of association (e.g. Cohen's d, Cramer's V). For patient-level outcomes, the oncology financial navigator will be treated as a fixed effect when needed. Primary analyses will use binomial logit models to estimate proportions of implementation outcomes (**Table 2**). Models will estimate time trends for implementation outcomes using a categorical coefficient for quarter. Model-predicted means and inverse-link transformations will be used to estimate proportions of implementation outcomes and respective 95% confidence intervals. Secondary analyses for patient-level outcomes will use logit models to evaluate the association between implementation outcomes and patient subgroups, including race (white, Black/person of color), residence (rural, urban), and insurance status (private, Medicare, Medicaid, other, uninsured). For secondary, oncology financial navigator-level outcomes, generalized linear mixed models with random effect for within-oncology financial navigator repeated measurements will be used to estimate the number of and time to positive financial hardship screens addressed. SAS Version 9.4 will be used for data analysis.

ii. Sample size: As Aim 1 is a secondary analysis of pragmatic, clinic-based, administrative data, these sample sizes are simply estimates dependent on implementation of oncology financial navigation within the UAB Medical Oncology clinic—*there will be no true enrollment*. As UAB is expecting to hire a minimum of 5 oncology financial navigators, our study will be powered on our primary analyses using patient-level data. UAB treats approximately 5,000 new patients with cancer per year. The UAB Cancer Service Line is planning to roll-out this service sequentially by cancer type, thus we anticipate ~1400 patients targeted to receive oncology financial navigation per year during the first two years of roll-out. As oncology financial navigation is standard of care provided to all patients and thus an opt-out program, we anticipate that 90% of patients will be willing to receive oncology financial navigation if approached. Thus, we anticipate at least 2,500 patients will receive oncology financial navigation over the 2-year duration of the funding period (n=1250/year). Under these assumptions, for patient-level analyses, the expected large sample size provides high power and precision to support our analysis of implementation outcomes.

b. **Aim 2. Evaluate oncology financial navigation effectiveness.**
   i. Statistical analysis: To compare outcomes for patients receiving oncology financial navigation and historical controls (patients with financial hardship screening data from 2020 to pre-oncology financial navigation implementation), we will use non-linear modeling (e.g. a Random Forest approach[41]) to estimate a propensity score to match navigated patients with historical controls using radius matching. If needed, we will use matching with replacement (i.e., a control patient could be matched with >1 patient receiving oncology financial navigation) to include as many patients receiving oncology financial navigation as possible. We will then use generalized linear or generalized linear mixed models to conduct between-group comparisons on financial and psychological outcomes. If matching with replacement is conducted, then cluster-level bootstrapping[42] (clusters indicated by the individual control patients) will be used to provide inference on these procedures. A False Discovery Rate approach will be used to correct for multiple inferences when appropriate (10% FDR). We will conduct sensitivity analyses to assess for changes in outcomes due to implementation strategies, local site changes, and national changes. SAS Version 9.4 will be used for data analysis.
   ii. Sample size: Given 800 historical controls with 6-month change scores, an estimated 800 navigated patients with 6-month change scores, and assuming a two-sided t-test between change scores with ICC=0.5, we expect a detectable effect size d=0.14 at 80% power and α=0.025. Using our UAB Medical Oncology historical patient-reported financial hardship screening data, this effect size corresponds to a difference in mean 6-month COST change scores of 1.5.

c. **Aim 3. Assess how implementation strategies were utilized to overcome barriers to oncology financial navigation.**
   i. Qualitative data collection and analysis: Videocall-based interviews will elucidate oncology financial navigation (1) implementation barriers, and (2) perceptions of how selected implementation strategies addressed barriers (**Table 1**). Interviews will be conducted by Dr. Williams (*PI*) using interview guides developed in conjunction with Dr. Turan (*co-mentor*) and the larger mentorship team (GR, LZ). Interviews will be recorded and digitally transcribed. The analytic strategy will be primarily informed by content analysis, which classifies text into categories that represent key concepts within interviews.[43] Qualitative coding and content analysis will consist of identifying quotations that express themes related to strategies utilized to overcome barriers to oncology financial navigation implementation. Two independent coders (CW, TP) will develop an initial open coding scheme, which is the process of labeling portions of text to identify all ideas and themes suggested by the data.[44] Analytic codes constructed in the context of open coding are provisional and will be grounded within the data.[45] The final version of the coding schema will be reviewed and finalized by the mentorship team (JT, GR, LZ). The two primary coders will then conduct “focused coding,” which includes a detailed

analysis of themes identified during open coding. Any discrepancies in coding will be discussed among the team and resolved. Dr. Rocque (*primary mentor*) has used this approach in prior studies and found it to be a useful strategy in evaluating program implementation.[46-48] The process will be repeated until thematic saturation is reached, where no new categories or relevant themes emerge.[49] Data from interviews will be analyzed at an aggregate and participant-specific level. Summaries will be reviewed with the mentorship team and used to understand implementation strategy effectiveness. DeDoose Version 9.0 will be used for qualitative analysis.

ii. Sample size: Qualitative sampling is often sequential, targeted to individuals who can provide insights on the processes under study, and typically involves <50 participants.[50] If thematic saturation is not reached at a sample level, we will increase the number of participants until saturation is achieved. Access to a diverse group of participants will provide a sufficient participant pool to carry out analyses. If an unexpected perspective is observed within a specific patient subgroup, we will interview an additional 5 participants from the subgroup to conduct negative case analysis.[51]

6. Data and Safety Monitoring

This study is intentionally designed to be an evaluation of largely secondary health system data used in routine patient care. Best judgment is required of all oncology financial navigators in entering, interpreting, and/or acting upon information gathered from the patient-reported data. Therefore, a data safety and monitoring board is not necessary, but a data and safety monitoring plan is required. Prior to study initiation, University of Alabama at Birmingham Institutional Review Board (IRB) approval will be obtained.

a. Aims 1&2: Data included in Aims 1&2 consist of electronic medical record (EMR)-abstracted sociodemographic and clinical data, EMR-embedded navigation software data, and EMR-embedded patient-reported data. There will be no primary data collection from patients or oncology financial navigators for this quantitative portion of the study. Therefore, a waiver of consent will be requested for this portion of the study. Patient monitoring, including financial hardship screening data, will be conducted as part of standard of care. If an oncology financial navigator notices any indication of financial distress or reasons for concern, s/he will conduct timely follow-up with the patient in accordance with standard protocols. Data for implementation outcomes and patient outcomes are also collected as part of standard of care. Access to patient data will be limited to the patient care teams and relevant study staff. Data will be de-identified when possible and encrypted to enhance security. When unique patient identifiers (unrelated to any patient characteristics) are required to track patient-level outcomes, the files will be sent via secure transfer and stored on secure encrypted network drives.

b. Aim 3: Qualitative interview data will be collected for Aim 3. All patient, provider, and health system participants will consent to study participation. All interview data from patient, provider, and health system interviews will be de-identified and securely stored on encrypted network drives at UAB. Access to interview data will be limited to the relevant study staff. Data will be de-identified when possible and encrypted to enhance security.

7. Benefits

Patients receiving standard-of-care oncology financial navigation may benefit by receiving support for cancer-related financial distress and/or difficulties.

8. Potential Risks and Solutions

a. Aims 1&2: Participants will not receive any clinical treatment as part of this study, minimizing physical risks. This project will utilize health and other personal information about the study participants. The primary risk to the participants will be loss of confidentiality leading to potential psychological, financial, or legal consequences. However, we believe the likelihood of confidentiality breach is very low.

b. Aim 3: It is possible that some patients may be unwilling to participate in interviews due to embarrassment or concern about sharing responses regarding financial navigation; however, participation is entirely voluntary. For providers and health system participants, their choice to participate in interviews will not impact their employment in any way. Participants may also drop

out at any time, which will be indicated in the consent form. Interviews will be kept as brief as possible to minimize participant burden. If participants have any questions or concerns, the PI will address them in a sensitive and professional manner.

9. Confidentiality

a. Aims 1&2:

i. All human subjects research described in this application will take place at UAB by investigators trained in the ethical conduct of human subjects research and in the use of protected health information. Protocols will be approved by the UAB IRB.

ii. The PI and quantitative data manager will meet weekly to discuss any issues pertaining to data handling, protection, confidentiality, and to provide additional training as needed during these discussions.

iii. Data will be protected for confidentiality as described in the Data Safety and Monitoring Plan. In previous experiences, the plans in place work well to protect against loss of confidentiality, and we anticipate they will continue to be effective. We will continue to review and update the plan as necessary, and we will maintain a work culture which stresses the importance of maintaining study participant confidentiality.

b. Aim 3:

i. Transcribed interviews will be de-identified and assigned a patient ID number. A list of assigned patient ID numbers will be kept on a password-protected UAB computer in a location different than where the transcribed files are stored. The videocall recording will be stored on an encrypted, password-protected computer at UAB. Names of persons, locations, and other personal identifying information will be replaced by generic codes following a coding scheme.

ii. The PI and qualitative data manager will meet weekly to discuss any issues pertaining to data handling, protection, confidentiality, and to provide additional training as needed during these discussions.

iii. Data will be protected for confidentiality as described in the Data Safety and Monitoring Plan. In previous experiences, the plans in place work well to protect against loss of confidentiality, and we anticipate they will continue to be effective. We will continue to review and update the plan as necessary, and we will maintain a work culture which stresses the importance of maintaining study participant confidentiality.

10. References

1. Altice CK, Banegas MP, Tucker-Seeley RD, Yabroff KR. Financial Hardships Experienced by Cancer Survivors: A Systematic Review. *J Natl Cancer Inst*. Feb 2017;109(2)doi:10.1093/jnci/djw205

2. Hastert TA, Banegas MP, Hamel LM, et al. Race, financial hardship, and limiting care due to cost in a diverse cohort of cancer survivors. *J Cancer Surviv*. Jun 2019;13(3):429-437. doi:10.1007/s11764-019-00764-y

3. Odahowski CL, Zahnd WE, Zgodic A, et al. Financial hardship among rural cancer survivors: An analysis of the Medical Expenditure Panel Survey. Journal Article. *Prev Med 129 Suppl:105881*. 2019;

4. Chino F, Peppercorn JM, Rushing C, et al. Out-of-Pocket Costs, Financial Distress, and Underinsurance in Cancer Care. *JAMA Oncol*. Nov 1 2017;3(11):1582-1584. doi:10.1001/jamaoncol.2017.2148

5. Lee M, Salloum RGJJoCS. Racial and ethnic disparities in cost-related medication non-adherence among cancer survivors. 2016;10(3):534-544.

6. Hastert TA, Kyko JM, Reed AR, et al. Financial Hardship and Quality of Life among African American and White Cancer Survivors: The Role of Limiting Care Due to Cost. 2019;28(7):1202-1211. doi:10.1158/1055-9965.EPI-18-1336 %J Cancer Epidemiology Biomarkers & Prevention

7. Ramsey SD, Bansal A, Fedorenko CR, et al. Financial Insolvency as a Risk Factor for Early Mortality Among Patients With Cancer. *J Clin Oncol*. Mar 20 2016;34(9):980-6. doi:10.1200/JCO.2015.64.6620

8. Samuel CA, Spencer JC, Rosenstein DL, et al. Racial differences in employment and cost-management behaviors in patients with metastatic breast cancer. *Breast Cancer Research and Treatment*. 2020/01/01 2020;179(1):207-215. doi:10.1007/s10549-019-05449-9

9. Biddell CB, Wheeler SB, Angove RSM, et al. Racial and Ethnic Differences in the Financial Consequences of Cancer-Related Employment Disruption. Original Research. *Frontiers in Oncology*. 2021-July-30 2021;11doi:10.3389/fonc.2021.690454
10. Palmer NRA, Geiger AM, Lu L, Case LD, Weaver KE. Impact of rural residence on forgoing healthcare after cancer because of cost. *Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology*. 2013;22(10):1668-1676. doi:10.1158/1055-9965.EPI-13-0421
11. Arozullah AM, Calhoun EA, Wolf M, et al. The financial burden of cancer: estimates from a study of insured women with breast cancer. *J Support Oncol*. May-Jun 2004;2(3):271-8.
12. Wheeler SB, Spencer JC, Manning ML, et al. Multidimensional financial hardship among uninsured and insured young adult patients with metastatic breast cancer. *Cancer Medicine*. 2023;12(10):11930-11940. doi:https://doi.org/10.1002/cam4.5885
13. Zahnd WE, Davis MM, Rotter JS, et al. Rural-urban differences in financial burden among cancer survivors: an analysis of a nationally representative survey. 2019;27(12):4779-4786.
14. Rocque GB, Williams CP, Hathaway AR, et al. Evaluating the Impact of Treatment Care Planning on Quality Measures. *J Oncol Pract*. Mar 2019;15(3):e271-e276. doi:10.1200/JOP.18.00390
15. Rocque GB, Dent DAN, Caston NE, et al. Building Sustainable Practice Transformation Through Payment Reform Initiatives. *JCO Oncology Practice*. 2022;18(5):e731-e739. doi:10.1200/op.21.00560
16. Rocque GB, Cadden A. Creation of Institute of Medicine Care Plans With an Eye on Up-Front Care. *J Oncol Pract*. Aug 2017;13(8):512-514. doi:10.1200/JOP.2017.023846
17. de Souza JA, Yap BJ, Hlubocky FJ, et al. The development of a financial toxicity patient-reported outcome in cancer: The COST measure. *Cancer*. Oct 15 2014;120(20):3245-53. doi:10.1002/cncr.28814
18. de Souza JA, Yap BJ, Wroblewski K, et al. Measuring financial toxicity as a clinically relevant patient-reported outcome: The validation of the COmprehensive Score for financial Toxicity (COST). *Cancer*. Feb 1 2017;123(3):476-484. doi:10.1002/cncr.30369
19. Williams CP, Liang MI, Rocque GB, Gidwani R, Caston NE, Pisu M. Cancer-Related Financial Hardship Screening as Part of Practice Transformation. *Medical Care*. 2023;61(12):S116-S121. doi:10.1097/mlr.0000000000001910
20. Doherty MJ, Thom B, Gany F. Evidence of the Feasibility and Preliminary Efficacy of Oncology Financial Navigation: A Scoping Review. *Cancer Epidemiol Biomarkers Prev*. Oct 2021;30(10):1778-1784. doi:10.1158/1055-9965.Epi-20-1853
21. Edward JS, McLouth LE, Rayens MK, Eisele LP, Davis TS, Hildebrandt G. Coverage and Cost-of-Care Links: Addressing Financial Toxicity Among Patients With Hematologic Cancer and Their Caregivers. *JCO Oncology Practice*. 2023;19(5):e696-e705. doi:10.1200/op.22.00665
22. Shankaran V, Leahy T, Steelquist J, et al. Pilot feasibility study of an oncology financial navigation program. 2018;14(2):e122-e129.
23. Sadigh G, Gallagher K, Obenchain J, et al. Pilot Feasibility Study of an Oncology Financial Navigation Program in Brain Cancer Patients. *J Am Coll Radiol*. Oct 2019;16(10):1420-1424. doi:10.1016/j.jacr.2019.07.014
24. Kircher SM, Yarber J, Rutsohn J, et al. Piloting a Financial Counseling Intervention for Patients With Cancer Receiving Chemotherapy. *Journal of Oncology Practice*. 2019;15(3):e202-e210. doi:10.1200/jop.18.00270
25. Yezefski T, Steelquist J, Watabayashi K, Sherman D, Shankaran V. Impact of trained oncology financial navigators on patient out-of-pocket spending. *Am J Manag Care*. Mar 2018;24(5 Suppl):S74-S79.
26. Watabayashi K, Steelquist J, Overstreet KA, et al. A Pilot Study of a Comprehensive Financial Navigation Program in Patients With Cancer and Caregivers. *Journal of the National Comprehensive Cancer Network J Natl Compr Canc Netw*. 01 Oct. 2020 2020;18(10):1366-1373. doi:10.6004/jnccn.2020.7581
27. Shelton RC, Chambers DA, Glasgow RE. An Extension of RE-AIM to Enhance Sustainability: Addressing Dynamic Context and Promoting Health Equity Over Time. Perspective. *Frontiers in Public Health*. 2020-May-12 2020;8doi:10.3389/fpubh.2020.00134

28. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*. Mar 2012;50(3):217-26. doi:10.1097/MLR.0b013e3182408812
29. Smith J, Norton W, DiMartino L, et al. A longitudinal implementation strategies tracking system: development and initial acceptability. AcademyHealth; 2020:
30. Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res*. Sep 2009;18(7):873-80. doi:10.1007/s11136-009-9496-9
31. Network NCC. NCCN clinical practice guidelines in oncology. *http://www nccn org/professionals/physician_gls/PDF/occult pdf*. 2008;
32. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. *Health Aff (Millwood)*. May-Jun 2008;27(3):759-69. doi:10.1377/hlthaff.27.3.759
33. Rocque G PM, Jackson B, Kvale E, Acemgil A, Taylor R, Demark-Wahnefried W, Kenzik K, Li Y, Martin M, Lisovicz N, Meneses K, Fouad M, Partridge E. Trends in Resource Utilization and Costs during Implementation of a Lay Navigation Program. presented at: American Society of Clinical Oncology Annual Meeting; 2015;
34. Rocque GB, Partridge EE, Pisu M, et al. The Patient Care Connect Program: Transforming Health Care Through Lay Navigation. *Journal of oncology practice / American Society of Clinical Oncology*. May 10 2016;doi:10.1200/JOP.2015.008896
35. Rocque GB, Taylor RA, Acemgil A, et al. Guiding Lay Navigation in Geriatric Patients With Cancer Using a Distress Assessment Tool. *J Natl Compr Canc Netw*. Apr 2016;14(4):407-14.
36. Smith JD, Merle JL, Webster KA, Cahue S, Penedo FJ, Garcia SF. Tracking dynamic changes in implementation strategies over time within a hybrid type 2 trial of an electronic patient-reported oncology symptom and needs monitoring program. *Front Health Serv*. 2022;2:983217. doi:10.3389/frhs.2022.983217
37. Powell BJ, Waltz TJ, Chinman MJ, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science*. 2015/02/12 2015;10(1):21. doi:10.1186/s13012-015-0209-1
38. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. Apr 2009;42(2):377-81. doi:10.1016/j.jbi.2008.08.010
39. Kind AJ, Buckingham WR. Making neighborhood-disadvantage metrics accessible—the neighborhood atlas. *The New England journal of medicine*. 2018;378(26):2456.
40. Flanagan BE, Gregory EW, Hallisey EJ, Heitgerd JL, Lewis B. A social vulnerability index for disaster management. *Journal of homeland security and emergency management*. 2011;8(1):000010220215477355179 2.
41. Efron B, Hastie T. *Computer Age Statistical Inference: Algorithms, Evidence and Data Science*. Cambridge University Press; 2016.
42. Field CA, Welsh AH. Bootstrapping Clustered Data. *Journal of the Royal Statistical Society Series B (Statistical Methodology)*. 2007;69(3):369-390.
43. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. Nov 2005;15(9):1277-88. doi:10.1177/1049732305276687
44. Pope C, Mays N. Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *Bmj*. Jul 1 1995;311(6996):42-5.
45. Miles MB, Huberman AM. *Qualitative data analysis : an expanded sourcebook*. 2nd ed. Sage Publications; 1994:xiv, 338 p.
46. Rocque GB, Dionne-Odom JN, Sylvia Huang CH, et al. Implementation and Impact of Patient Lay Navigator-Led Advance Care Planning Conversations. *Journal of pain and symptom management*. Apr 2017;53(4):682-692. doi:10.1016/j.jpainsymman.2016.11.012

47. Cartmell KB, Young-Pierce J, McGue S, et al. Barriers, facilitators, and potential strategies for increasing HPV vaccination: A statewide assessment to inform action. *Papillomavirus Res*. Dec 7 2017;5:21-31. doi:10.1016/j.pvr.2017.11.003
48. Yoong J, Park ER, Greer JA, et al. Early palliative care in advanced lung cancer: a qualitative study. *JAMA Intern Med*. Feb 25 2013;173(4):283-90. doi:10.1001/jamainternmed.2013.1874
49. Strauss J CA. *Basics of Qualitative Research*. Sage Publications, Inc.; 1990.
50. Polit DF, Beck CT. *Nursing Research: Generating and Assessing Evidence for Nursing Practice, 10th Ed.* Wolters Kluwer; 2017.
51. Hymer C, Smith AD. Harnessing the Positive Side of Negative Cases: Exemplars and Queries for Qualitative Researchers. Academy of Management Briarcliff Manor, NY 10510; 2022:14341.

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research:	Evaluating the implementation and impact of standard-of-care delivered oncology financial navigation
UAB IRB Protocol #:	IRB-300012763
Principal Investigator:	Courtney P. Williams, DrPH
Sponsor:	UAB Department of Medicine Research Excellence Advancement and Mentorship (DREAM) Council

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose is to assess perceptions of how selected oncology financial navigation implementation strategies were used to address implementation barriers.
Duration & Visits	You will complete a 30-60-minute-long interview.
Overview of Procedures	Videocall-based interviews to understand oncology financial navigation (1) implementation barriers, and (2) perceptions of how selected implementation strategies addressed barriers.
Risks	The greatest risk is loss of confidentiality.
Benefits	None.
Alternatives	If you do not want to take part in the study, then your alternative is not to participate.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose is to assess perceptions of how selected oncology financial navigation implementation strategies were used to address implementation barriers. This study will include patients who received oncology financial navigation, providers (oncology financial navigators, social workers, nurse managers, oncologists), and health system administrators (billing specialists, cancer service line leadership). We are planning to enroll approximately 20 patients, 10 providers, and 10 health system administrators from the University of Alabama at Birmingham (UAB).

Study Participation & Procedures

If you participate the study, you will also be asked to complete a 30-60-minute-long interview. During the interview, you will be asked questions about oncology financial navigation (1) implementation barriers, and (2) perceptions of how selected implementation strategies addressed barriers. This interview will take place over videocall. Your interview session will be audio-recorded, transcribed, and stored on secure and encrypted devices.

Risks and Discomforts

The greatest risk is breach of confidentiality. The study staff will protect your data so that your information will be kept private and will not release this information to anyone outside of authorized study personnel. The chance that this information will be given to someone outside of the authorized study personnel is very small. For patients, you do not have to answer any questions that you do not wish to answer as it may be uncomfortable talking and answering questions about

your experience with oncology financial navigation. For providers and health system participants, your choice to participate in interviews will not impact your employment in any way. You may also drop out at any time. Interviews will be kept as brief as possible to minimize burden.

Benefits
Patients receiving standard-of-care oncology financial navigation may benefit by receiving support for cancer-related financial distress and/or difficulties.

Alternatives
Your alternative is not to participate in this study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study scientist must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out information about you?
Information about your health may be used and given to others by the study scientist and staff. They might see the research information during and after the study.

- UAB staff involved with this research study

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the scientists, physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)

- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham – the scientists, physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, or University of Alabama Health Services Foundation, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study scientist. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others, including others outside of UAB, without your permission.

<u>Voluntary Participation and Withdrawal</u>
Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study scientist if you want to withdraw from the study.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There will be no cost to you for taking part in this study.

Payment for Participation
You will receive a $50 participation incentive. You will receive no other payment for your participation in the study. You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Questions
If you have any questions, concerns, or complaints about the research. You may contact Dr. Courtney Williams by telephone at (205) 975-0462 or the study manager Ms. Stacey Ingram by telephone at (205) 934-5287. They will be glad to answer any of your questions.

If you have questions about your rights as a research participant at UAB, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures
Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant **Date**

Signature of Person Obtaining Consent **Date**