Study Protocol Title:
Building on Trust: Navigating Preventive Lung, Breast, and Prostate Cancer Screenings at Community Resource Spots

Study Sponsor:
AdventHealth and State of Florida, Department of Health

Principal Investigator:
Mark Socinski, MD

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Introduction

This document is a protocol for a human research study. This study is to be conducted in accordance with AH institutional research requirements and all federal regulations.

Background Information and Scientific Rationale

Screening for cancer in asymptomatic adults can lead to early detection, which has a notable impact on the cost of care and on patient outcomes. It is estimated that in the first year after diagnosis (2017), the cost of treating Stage IV cancer, compared to Stage I, is increased per patient by $37,661 for breast cancer, $18,086 for prostate cancer and $33,128 for lung cancer (Kakushadze, Raghubanshi, & Yu, 2017). Adjusting for inflation (2024), those approximate cost increases per patient would be $48,959 for breast cancer, $23,512 for prostate cancer and $43,066 for lung cancer.

In addition, patients who are uninsured are significantly more likely to receive a late-stage diagnosis. In Florida, uninsured patients were 46.9% more likely to be diagnosed with a high-grade lung cancer, 50% more likely to be diagnosed with late-stage breast cancer, and 39% more likely to be diagnosed with late-stage prostate cancer (Sasaki, Parianos, & Rahman, 2021). Those in high poverty areas in Florida, both rural and urban, have increased likelihoods of late-stage diagnoses, and the overall cancer-related mortality rate was 22% higher in high poverty areas than in low poverty areas, including lung (risk ratio 1.24), breast (risk ratio 1.17), and prostate (risk ratio 1.29) cancers (Hall et al., 2022; Hall et al., 2023).

In terms of mortality, the overall survival rates for early stage compared to late is 99% to close to 30% for breast cancer, 64.4% to 7.6% for lung cancer, and 100% to 33.5% for prostate cancer (National Cancer Institute, 2024). In light of this, uptake in screening and early diagnosis could have tremendous impact on cancer survival outcomes for this vulnerable and underserved population.

Advances in novel and innovative approaches to cancer treatment are saving and improving lives. However, racial and ethnic minority groups and medically underserved populations continue to experience multilevel barriers to screening, timely diagnosis, and access to treatment. Integrating an Implementation Science framework is an opportunity to promote the adoption, use, and sustainability of interventions and clinical trials in community-based clinical settings to improve uptake of cancer screening, preventive services, timely follow-up of abnormal findings, and referral to accessible care among adults experiencing social and structural barriers to health.

This proposal aims to reduce disparities in cancer care and outcomes for underserved Central Florida adults by increasing rates of lung, breast, and prostate cancer screenings. Distrust and lack of access to primary care are barriers to screenings and early detection. Collaborating with established community organizations and identifying reasons to accept or decline care will allow us to offer sustainable community-based cancer screenings that result in increased cancer diagnosis and treatment.

We hypothesize that implementation of a community-based multi-disciplinary navigation team will foster improved cancer screening rates, financial navigation to facilitate timely definitive diagnosis and treatment regimens, as well as screening for clinical trial eligibility among underserved individuals. Effective patient navigation promotes access to timely treatment by overcoming barriers to care. Hospital-based patient navigation programs for cancer and chronic diseases have been well-established in improving screening rates and diagnostic resolution (Chen et al., 2024). Cancer-related financial hardship is an additional result of cancer diagnosis and treatment, and therefore of increased national interest (SWOG Cancer Research Network, 2024). While some oncology clinics provide financial navigation services, few community-based health care clinics have sufficient resources to proactively facilitate financial counseling and assistance ultimately delaying cancer screening, definitive diagnosis, and successful treatment (Bell-Brown et al., 2023).

Study Objectives

Primary Objective/Aim/Goal/Hypothesis

To evaluate a community-based outreach initiative for screening, diagnosis, and treatment of breast, lung, and prostate cancers in underserved adults using the RE-AIM implementation science framework.

Secondary Objective/Aim/Goal/Hypothesis

Secondary goals include:

- To identify differences between adults who accept or decline cancer follow-up diagnosis and treatment, and clinical trial screening
- To identify barriers and facilitators to cancer screening, diagnosis, treatment, and clinical trial screening
- To understand perceptions towards navigators in the cancer care continuum

Study Design

Research Design

The research strategy will employ a prospective, mixed methods implementation science design based on the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework.

Reach will include the number of patients in the community that are offered and undergo cancer screening. Effectiveness will be determined by comparison of monthly breast, lung, and prostate cancer screening referral uptake to baseline. Adoption will be evaluated by the number of patients with positive screens that are referred for screening and for treatment. Implementation will occur via the cyclical improvement triad approach that includes repeated evaluation and modification to ensure that barriers to care are addressed. Maintenance and sustainability will be supported by the return on investment by early cancer detection and treatment.

Research Intervention Description

The proposed intervention integrates cancer screenings at pop-up clinics located at community resource spots in partnership with well-established community-based organizations for the underserved, as well as in local emergency departments that serve this population. Currently, cancer screenings are offered as standard of care in primary care settings; however, this population rarely has access to primary care. Instead, this population often seeks episodic care for symptom management and does not benefit from preventive care services in primary care settings. Integrating cancer screenings into episodic care will be accomplished through a multi-faceted approach which includes leveraging a team of navigators to help connect those with positive screening results to community health resources, treatment financial advocacy, care coordination, and access to screening for clinical trials. Navigators will guide access to a continuum of care including diagnosis, treatment, and clinical trials.

National guidelines exist for primary care providers to conduct annual screenings to detect and treat common cancer tumors before they progress to systemic disease. These guidelines are not routinely followed in non-primary care settings, like pop-up clinics and emergency rooms. The study team will provide education to community-based healthcare providers on United States Preventive Services Taskforce Screening Guidelines for breast, lung, and prostate cancers. The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years. The USPSTF recommends biennial screening mammography for women aged 40 to 74 years. The USPSTF recommends that the decision to undergo periodic prostate-specific antigen (PSA)-based screening for prostate cancer should be an individual one among men aged 55 to 69 years. All participant-facing education materials will be reviewed and approved the Institutional Review Board (IRB) before use in the research study.

Screenings will take place at pre-established pop-up clinics associated with community-based outreach organizations or other settings such as emergency departments and urgent care centers where patients may show for symptom management and result in a positive screen. A bilingual field- and a bilingual hospital-based navigator will connect participants with screening (e.g. mammograms) and confirmatory diagnostics, treatment and/or clinical trials when applicable. In addition, a financial navigator will identify free and reduced cost diagnostic testing and assist with Medicaid enrollment and other financial aspects of care for patients who screen positive.

Study Site(s)/Location(s) and Number of Subjects

AdventHealth sites (hospital(s), campus, physician offices, etc): AdventHealth Central Florida Division (e.g., AdventHealth Apopka, AdventHealth East Orlando, AdventHealth Kissimmee) emergency departments, CentraCare locations
Estimated number of subjects at AdventHealth sites: Unable to determine until screenings provided

Name of external site(s) outside of AdventHealth: Community health clinics or health systems willing to provide free or low-cost diagnostics to under-resourced patients on referral
Estimated number of subjects at external sites: Unable to determine until screenings provided

Total number of all sites: 20
Estimated number of subjects at all sites combined: 200

Multi-Site Research Logistics/Communication Plan
N/A

Research Conducted in a Foreign Country
N/A

Community-Based Participatory Research
N/A

Subject Selection

Vulnerable Populations (if applicable)
N/A

Inclusion Criteria
The inclusion criteria for patients will be the following:
1. Adult aged 18 or older
2. Seeking care at a CRS or emergency department
3. Meets criteria for lung, breast, and/or prostate cancer screening, as outlined below:
    a. Lung cancer: Adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years
    b. Breast cancer: Women aged 40 to 74 years
    c. Prostate cancer: Men aged 55 to 69 years
4. Receives a positive screening result for lung, breast, and/or prostate cancer at a study site

The inclusion criteria for stakeholders will be the following:
1. Speaks English or Spanish through study interpreters
2. Able to attend 75% or more of scheduled meetings
3. Must be key individuals providing critical services to address food insecurity, employment assistance, government support, mental and physical health, and health education within identified Community Resource Spots, emergency departments, and urgent care centers.

Exclusion Criteria

The exclusion criteria for patients will be the following:

1. Displays behavior disruptive to other patients or staff
2. Refusal to accept screening for breast, lung, and/or prostate cancers

The exclusion criteria for stakeholders will be the following:

1. Speaks language other than English or Spanish
2. Unable to attend 75% or more of stakeholder meetings

Resources Available

Research Personnel Qualifications

All members of the study team are employed by AdventHealth in full-time positions with training in research processes and methodologies. All personnel have completed the necessary AdventHealth IRB training and credentialing requirements. A study start-up meeting will be held to describe the research study and clarify each team member's duties and functions. Biweekly meetings will be held either in person or by teleconference for the duration of the study to review the study and to ensure that the protocol is being followed, report the study progress, share reportable information, and implement any amendments made to the protocol.

The research team will be comprised of a principal investigator, implementation scientists, qualitative researcher, RN clinical research study coordinator/clinical educator, statistician, project managers, cancer care navigator, financial navigator, research trials navigator, community outreach coordinator, advanced practice provider (APP), data manager, and information architect. As these individuals are hired and/or added to the research team, the delegation log will be revised to include them.

Study Procedures

Subject Recruitment and Screening

Recruitment of Stakeholders

Investigators will establish relationships with community stakeholders, providers, and other key personnel to inform them of the program, the study, and opportunities to engage in stakeholder focus groups to provide feedback about program operations. For those interested in participating, a study team member will explain the study and the requirements for participation, review the informed consent form in detail, and obtain consent.

Recruitment of Patients

Patients undergoing screening as standard of care will have access to clinic-based educational materials, i.e. signage and pamphlets in English and Spanish on cancer screening, diagnosis and care and on the study opportunity.

As standard of care for patients who screen positive, a care navigator will be assigned. The care navigator will provide patients with study recruitment materials and information, ensuring patients are aware that study involvement does not impact care navigation or treatment.

After positive breast, lung, and/or prostate cancer screening in the field or at an emergency room or care facility, study team members will be informed of positive field screens. Patients with positive screens will be referred for confirmatory diagnostic testing and will receive guidance from care navigator and the financial navigator to set up appointments. A study team member will meet the potential participant at the site of diagnostic testing and/or at emergency departments or other urgent care sites to introduce the study and obtain informed consent for research activities.

Consent Process

The researchers will follow SOP CW AHC 216 Informed Consent Process and Written Documentation of Informed Consent. Also, the researchers will follow SOP CW AHC 249 Remote and Electronic Methods for Conducting Informed Consent in Non-Exempt Research.

For Patients: Upon referral for definitive diagnosis based on their cancer screening results, patients will be contacted by a study team member for informed consent for survey completion, interviews and electronic health record access to monitor outcomes. All consent forms will be completed on paper or electronically via REDCap on a tablet device provided by the study team.

For Stakeholders: Study team members will contact community stakeholders in person, or via phone or email to re-explain the study and obtain consent. Consent forms may be completed on paper or electronically via REDCap.

Subjects who are not yet adults (infants, children, teenagers)

N/A

Cognitively Impaired Adults

N/A

Adults Unable to Consent

N/A

Documentation of Informed Consent Process

A member of the study team will note the following in the Enrollment Log: the participant's name, phone number, email address (if applicable), the date of screening, the date the informed consent was signed, whether inclusion/exclusion criteria were met (and reason if excluded), screening outcome, completion of study or withdrawal (and reason if withdrawal), and investigator terminated (and reason) if applicable. The Enrollment Log will be saved in the shared Microsoft OneDrive folder.

Waiver of Written Documentation of Consent or Waiver of Consent

Waiver of Written documentation of Consent (consent will be obtained but signatures will not be required)
N/A

Waiver or Alteration of the Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)
N/A

Waiver or Alteration of HIPAA Authorization
N/A

Non-English Speaking Subjects

x Check here to confirm you will follow HRP-804 INVESTIGATOR GUIDANCE Short Form Consent Process

Consent forms and all study materials will be translated into Spanish for both Spanish-speaking patients and stakeholders.

For patients and stakeholders that speak Spanish as a primary/preferred language, the study team will ensure that a Spanish-speaking research team member is in place to navigate the consent process, study activities, provide directions, and guidance on next steps.

For patients:
Spanish-speaking participants will be included only in surveys that are validated in English and Spanish. Spanish-speaking participants will be eligible for focus groups and interviews with a Spanish-speaking team member.

Those patients who do not speak English or Spanish as a primary language will be consented appropriately using a consent form that is fully translated and provided to the participant as soon as possible. These individuals will be eligible for medical record tracking for follow-up but will not participate in surveys or interviews.

For all non-English speakers, short form consents will be utilized using medical translators until regulatory requirements dictate translation of consent.

Randomization

N/A

Study Visits

For patients, study visits include:

- Consent and enrollment and at the site of confirmatory diagnostics and/or emergency room or healthcare center

- 1 or more interviews with the research team throughout the study period
- Survey package completion with coordinator at a site of diagnosis or care

Study Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Consent/Enrollment	X							
Baseline Surveys		X						
First Interview			X					
3-Month Surveys				X				
Optional Follow-Up Interviews					X	X	X	X

For stakeholders, study visits include:

- Consent and enrollment
- Ongoing stakeholder meetings throughout the duration of the study up to 12.
- 1 or more interviews with the research team throughout the study period.

Study Visit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Consent/Enrollment	X																	
Stakeholder Meetings		X	X		X	X		X	X		X	X		X	X		X	X
First Interview				X														
Optional Follow-Up Interviews							X			X			X			X		

Study Duration

The project is projected to begin on August 1, 2025. Study subjects will be enrolled for 9 months. Participants will remain active in the study until they have received a definitive diagnosis and treatment plan or declined further care. The study activities, including data analysis, will be completed within 12 months from the start date.

The implementation plan that details study activities and timelines will be developed according to current best practice for evaluating effectiveness and will be informed by input from the stakeholder group at each site. The implementation plan is as follows:

- Month 1: Finalize key stakeholders at each site and initiate monthly implementation meetings with study team and including stakeholders as needed, collect baseline data and initiate ongoing data gathering (i.e., lung, breast, prostate cancer screening knowledge, attitudes, and practices, cancer screening barriers and facilitators), establish care navigation and communication processes and launch project.
- Month 2: Data collection and monitoring of all sites, implementation meetings.
- Month 3: Data collection and monitoring of all sites, implementation meetings.
- Month 4: Data collection and monitoring, implementation cycle 1 adjustments, stakeholder meetings for data sharing and plans, patient study enrollment.
- Months 5-7: Continue monthly implementation meetings, data collection, study enrollment, data-driven process improvement.
- Month 8: Stakeholder meetings, implementation cycle 2 adjustments.

- Months 9-10: Continue monthly implementation meetings, data collection, study enrollment, process improvement.
- Month 11: Final data collection and analyses.
- Month 12: Final reporting, stakeholder meeting and sustainability plan development.

	FL CANCER FUND PROJECT PERIOD MONTHS											
	1	2	3	4	5	6	7	8	9	10	11	12
Implementation plan finalized	X											
Implementation plan socialized	X											
Stakeholder meeting (x # sites)	SM	SM	SM	SM	SM	SM	SM	SM	SM	SM	SM	SM
Active Implementation period	Zipcode 1	MONITORING/ADJUSTMENTS AS NEEDED										
		Zipcodes 2 & 3	MONITORING/ADJUSTMENTS AS NEEDED									
Implementation Iteration cycles				Cycle 1				Cycle 2				
Data collection	BASELINE	X	X	X	X	X	X	X	X	X	FINAL	
Interview themes + Quantitative data review		X	X	X	X	X	X	X	X	X	X	X
Reporting requirements			PR due			PR due			PR due			FR due

Materials of Human Origin: Collection, Preparation, Handling and Shipping

N/A

Study Outcome Measures (Endpoints)

Dashboard and Records

There will be an information architect on the study team who will build and maintain a dashboard to track the project metrics. These metrics can be categorized into the RE-AIM model dimensions of Reach, Effectiveness, Adoption, Implementation, and Maintenance, which are outlined below.

- **Reach**
  - Percentage and characteristics of patients included or excluded
  - Percentage of patients who receive screening at point of care or referral
  - Characteristics of participants and non-participants
- **Effectiveness**
  - All positive screens referred for confirmatory diagnostics
  - Measure of screening rates with comparison to the goals set forth in Healthy People 2030 (HP2030)
    - Increase the proportion of adults aged 55 to 80 years (30-pack-year smoking history, currently smoking or quit in the past 15 years) who receive a lung cancer screening to meet the HP2030 target of 7.5%
    - Increase the proportion of females aged 40 to 74 years who receive biennial screening mammography to meet the HP2030 target of 80.3%
    - Increase the proportion of men ages 55 to 69 years that discuss the possible benefits and harms of prostate-specific antigen (PSA) screening with their health care provider and make an individualized decision about whether to get screened
- **Adoption**
  - Percentage of providers who receive education on screening guidelines for breast, lung, and prostate cancer
  - Uptake of cancer screening in the field by number of providers

    - Percentage of provider staff that engaged with navigation program
- **Implementation**
    - Number of patients referred to navigation program
    - Rates of 1) low dose CT lung cancer screens 2) biennial screening mammography, and 3) prostate specific antigen (PSA)
    - For those who have a positive screen: 1) time to referral, 2) time and barriers/facilitators to diagnosis 3) uptake of treatment, and 4) number screened for clinical trials
- **Maintenance**
    - Measure of primary outcomes at 3 months post-intervention with progress towards Healthy People 2030 goals
    - Short-term attrition rate
    - Differential rates by patient characteristics

Medical records will be followed until definitive diagnosis and treatment disposition to track the patients' progress through the cancer care continuum. If diagnosis is negative, then interaction with the medical record ends upon confirmation of negative test. If diagnosis is positive, then the medical record is followed monthly to determine: diagnostic codes, treatment decisions, treatment course, and treatment outcomes. This may include labs, demographics, medication histories, referrals, outpatient visit notes, inpatient progress notes, and imaging.

Patient Participants – Quantitative

English-speaking patients will complete a package of surveys regarding health and perceptions of cancer navigators. Patient demographics will be obtained to include age, race, ethnicity, sex and gender, marital status, primary language, birth country, employment, education level, household income, insurance and type, housing/shelter, food, transportation insecurity, and environmental safety.

Patient-reported outcomes will occur at baseline and 3-month follow-up. These outcomes will include the PROMIS Global Health (HR-QoL) scale (Hays et al., 2009) to ascertain health-related quality of life to assess physical, mental, and social health and the Patient Satisfaction with Logistical Aspects of Navigation Scale (PSN-L) (Carle et al., 2014) to assess satisfaction with the navigation program. Additionally, barriers will be measured by the barriers to cancer care assessment used in the NCI Patient Navigation Research Program (Freund et al., 2008).

Patient Participants – Qualitative

Patients will be invited to participate in interviews regarding decision points in diagnostics and care. They will be invited to at least one, and up to five, interviews with a study team member. Interviews will be no longer than one hour each. Virtual interviews will take place via video conferencing software and will be recorded and transcribed electronically. In-person interviews will be recorded with a portable digital recording device and will be manually transcribed. An open-ended interview guide will be available in English and Spanish. Both versions will be IRB-approved prior to use. Questions regarding barriers and facilitators to cancer diagnosis and the care continuum will be addressed in addition to process and program feedback for improvement.

Stakeholder Participants – Qualitative

Stakeholders will be invited to participate in interviews and/or focus groups about their knowledge, attitudes, and practices related to cancer screening processes, as well as the RE-AIM model dimensions. They will be invited to at least one, and up to five, interviews with a study team member. These will occur over the 12-month study period, alongside the monthly stakeholder focus group meetings. Interviews/focus groups will be no longer than one hour each. All stakeholder interviews/focus groups will take place via video conferencing software and will be recorded and transcribed electronically.

Questions will be asked to further the understanding of factors influencing reach, screening, and study recruitment (Reach), effectiveness and impact on outcomes (Effectiveness), and staff participation (Adoption), as well as implementation facilitators and barriers for screening, diagnosis, treatment, and clinical trials (Implementation). An open-ended interview guide will be available in English and Spanish.

Qualitative data gathering will inform timely actionable changes to improve cancer screening, identification, treatment, and outcomes. Other *ad hoc* groups will be formed as needed to address specific questions or concerns that arise in processes or from feedback.

Data Management and Quality Plan

Data De-identification

Participants will be added to the EDC system called REDCap using a unique participant identification number (PID). This PID is a code consisting of a combination of numerals and letters, which will serve as the identifier for this participant for this study. Access to the "link" between PIDs and participants' identities will exist only in the Enrollment Log and the EDC, which can only be accessed by study team members.

Survey data will be exported from REDCap in Excel format. An Excel file used for analysis will be de-identified and only include the PIDs. The storage location will be secured and only accessible by study team members in the Microsoft OneDrive folder.

All interview data will have names deleted and replaced with a unique identifier for the participant.

The electronic health record data that is collected as part of a clinic visit will be added in a de-identified manner (i.e., by the PID) to the Excel file used for analysis and stored securely in the Microsoft OneDrive folder that is only accessible by study team members.

Data Confidentiality, Storage, and Retention

The participants' identities will be kept confidential to the extent permitted by the applicable laws and/or regulations and will not be made publicly available. If study results are published or presented, participants' identities will not be revealed. Confidentiality will be maintained during and after the study.

Study documentation and data records will be stored as electronic records. All data are safeguarded so that only members of the study team have access to it via role relationship (electronic). The electronic data are maintained under AIT security controls. Email addresses of enrolled participants will be stored in the shared folder and will be retained for 7 years following study closure. Electronic de-identified data will also be kept in our database for 7 years. Paper records, if any, will be stored in a locked facility for 7 years.

For qualitative interviews, an interview transcript will be obtained using transcription from the Microsoft Teams recording. Alternatively, an audio file will be obtained through portable digital recording device and will be transcribed. A member of the research team will verify the accuracy of transcriptions. The recording and transcript of the interview on Microsoft Teams, as well as the original audio file on the portable digital recording device, will be deleted after transcription is complete and verified. Participants will be advised that Microsoft Teams saves a record of the meeting via the Chat feature indefinitely. Transcripts will be saved electronically on the personal protected drive of the qualitative researcher. All identifiable information will be deleted from transcripts and replaced with a unique identifier based on participant role, e.g. CRS Stakeholder 1; Provider 1.

Data Quality

Participants will complete all surveys electronically through REDCap, and this data will be exported into an Excel file, limiting the need for transcription and potential errors to occur. Quality of qualitative data will be ensured by checking transcripts against recordings of focus groups and interviews.

Data Sharing

N/A

Sample Size Determination

Sample sizes for the qualitative data component of implementation research range between five and 10 key stakeholders to provide sufficient information power and saturation (Hamilton & Finley, 2019).

Sample size for patients will be a convenience sample based on the number of positive screens. Approximately 10% of those screened for breast cancer require follow-up diagnostics (Kumar et. al, 2020), 20% of those screened for lung cancer require follow-up diagnostics (Babar et. al, 2023) and 6-20% of those screened for prostate cancer require follow-up diagnostics (McFall & Smith, 2009).

Statistical Analysis Plan

Primary Objective Analysis

Patient-reported demographic characteristics will be analyzed using descriptive statistics associated with the **Reach** aim. To address the **Effectiveness** aim pre- and post-intervention barriers data and patient-reported outcomes will be analyzed using univariate, bivariate, and repeated measures analyses. Referral data will be

descriptively evaluated based on percent increase/decrease across the intervention. Qualitative data will be analyzed to determine the extent to which the **Adoption** aim was met. Analyses of the fidelity of the intervention, including timeliness and consistency will be documented as part of the **Implementation** aim. Finally, process-level descriptions, including the summation of monthly team meetings and direct communications with the Implementation Scientist of the community-focused multi-disciplinary navigation intervention will be used to assess the **Maintenance** aim.

Secondary Objective Analysis

Qualitative analysis will be utilized to explore and explain influential factors for each RE-AIM dimension (Holtrop, Rabin, & Glasgow, 2018). Transcripts from interviews, field observations, and stakeholder meetings will be analyzed utilizing thematic analysis to explore factors that influence uptake patterns across patients, providers, navigators, and implementation sites (Braun & Clarke, 2006). Prompt turnaround of qualitative data analyses will inform timely action plans with stakeholders (Kowalski et al., 2024; Lewinski et al., 2021).

Potential Risks and Benefits

Potential Benefits

There are no direct benefits of participation.

Potential Risks

There are no risks involved beyond what would reasonably be encountered in everyday life. It is possible that participants may experience the following during the study:

- Loss of privacy as a result of a breach of confidentiality
- Undue stress related to the questionnaires which ask about physical and emotional well-being

Mitigation of Risks

Participants will be informed that measures are in place to prevent the loss of privacy and to protect data, such as deidentification of responses and the use of HIPAA-compliant electronic data capture system. In addition, the organization has safeguards in place to secure information technology. Participants will be given hotline numbers for mental health support if needed.

Provisions to Protect the Privacy Interest of Subjects

The protection of study participants will be accomplished by adhering to ethical and legal guidelines. All policies for the protection of human subjects mandated by the AdventHealth IRB and U.S. Federal Guidelines for conducting research with human subjects will be followed. Subjects will be assigned unique identifiers for study-related records. Precautions will be taken to make sure that only authorized individuals will access subject research records. The collection of sensitive information about subjects will be limited to the minimum necessary to achieve the aims of the research so that no unneeded sensitive information will be collected.

Early Withdrawal of Subjects

Investigator Withdrawal of Subjects

Participants may be withdrawn from the study if they are unable or unwilling to comply with the study protocol.

Subject Request for Withdrawal from Study

Participants may request to be withdrawn from the study at any point for any reason without penalty by notifying a member of the study team.

Data Collection and Follow-up for Withdrawn Subjects

Participants who are withdrawn from the study for any reason will have their previous data included in summary reports (i.e., baseline characteristics) and pre-post comparison analyses up to the point of withdrawal unless they specifically request that their data be excluded from future use. They will be counted in the participant flowchart. A study team member will contact participants who do not complete the entire research study to find out the reason(s) to guide future program development and improvement.

Adverse Events - Recording and Reporting

All adverse events will be reported in accordance with AdventHealth IRB guidelines and documented using the HRP-204 form for Promptly Reportable Information.

Safety Monitoring Plan

Safety Monitoring

N/A

Data and Safety Monitoring Board (DSMB) or Equivalent

N/A

Ethical Considerations

All members of the study team will adhere to standards of ethical conduct during the study. To ensure the integrity of the research, members of the study team will adhere to all components of the protocol. Members of the study team will ensure that all potential participants are provided with informed consent, consent is obtained, and all participants have all questions answered before performing any study procedures. Members of the study team will ensure that participation is voluntary by noting that participants may withdraw from the study at any time without consequence.

Sharing of Results with Subjects

Participants will not receive a copy of the manuscript of the study once it is completed. However, dissemination of the project is anticipated.

Funding Source

This study will be supported by funding from the State of Florida, Department of Health (2265446). The IRBNet # for this grant is 2338019.

Subject Stipends or Payments

Patient participants will receive $25 for participating in the study. Provider participants will receive up to $240 for participating in the study (i.e., receive $20 after each completed monthly stakeholder meeting). These payments will be distributed through Greenphire payment cards. The Terms and Conditions for the card will be provided to participants for review.

Publication Plan

The study results will be reported to AdventHealth leadership and the Florida Department of Health. The study results will also be submitted for publication in a peer-reviewed journal. An authorship plan describing the assignment of authorship and each author's contribution will be completed based on the guidelines by the International Committee of Medical Journal Editors (ICMJE).

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