BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-067270
Article Type:	Protocol
Date Submitted by the Author:	08-Aug-2022
Complete List of Authors:	Suen, Jonathan; Johns Hopkins University, School of Nursing; Johns Hopkins University Bloomberg School of Public Health Parrillo, Elaina; Johns Hopkins University, School of Nursing Hassoon, Ahmed; Johns Hopkins Medicine; Johns Hopkins University Bloomberg School of Public Health Peairs, Kimberly ; Johns Hopkins Medicine Sidney Kimmel Comprehensive Cancer Center; Johns Hopkins Medicine Stanford, Olivia; Johns Hopkins Medicine Sidney Kimmel Comprehensive Cancer Center; Johns Hopkins Medicine Wenzel, Jennifer; Johns Hopkins University, School of Nursing; Johns Hopkins Medicine Sidney Kimmel Comprehensive Cancer Center Zabora, James; Johns Hopkins Medicine Dobs, Adrian; Johns Hopkins Medicine
Keywords:	ONCOLOGY, Adult oncology < ONCOLOGY, PUBLIC HEALTH

Improving Cancer Care for Underserved Populations in an Academic and Community Practice Setting: A Protocol for a Community Health Worker Pilot Navigation Program

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Word Count: 3,663

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ABSTRACT

Introduction: Delaying initial cancer treatment following first diagnosis impacts health outcomes, including increasing patient distress and odds of mortality. Interventions to promote timely health care engagement may decrease patient-reported stress and improve quality of life. Community health workers (CHWs) delivering problem-solving interventions represent an *enabling resource* for reducing delays in attending a patient's initial oncology treatment visit. We will implement a pilot CHW navigation program that guides patients and their caregivers in problem orientation and problem-solving for engaging their health care. We aim to understand how the program influences patients' health care utilization within the period between their first diagnosis to initial treatment visit.

Methods and Analysis: We will employ a hybrid implementation design to introduce the CHW navigation program at the centralized call center for the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center (SKCCC). CHW team members will use a consecutive sampling approach and call all eligible patients with cancer diagnoses. Participants will identify their cancer-related problems through the Problem-Checklist and CHWs will provide guidance by sharing relevant information. We will evaluate patients' time to initial oncology treatment and health care utilization through reviewing data from the electronic medical records at three- and six-months post-intervention. Bivariate analyses will be completed to evaluate the relationships between receiving the program and all outcome measures. We will employ independent t-tests to assess the program's impact on participant stress, quality of life, number of problems reported, and health care utilization.

Ethics and Dissemination: This study's protocol was thoroughly reviewed and approved by the Johns Hopkins School of Medicine's institutional review board (IRB). Dissemination planning is ongoing through regular meetings between members of the investigator team and public members of a long-established community advisory group (CAG). Study plans include

collaborating with other experts at the Johns Hopkins Medical Institutions for ideating dissemination strategies.

Keywords: cancer, community health workers, health equity, patient navigation, quality of life

STRENGTHS AND LIMITATIONS OF THIS STUDY

- *Limitation:* The target sample would be a heterogeneous population given the lack of an exclusion criterion based on cancer type
- *Limitation:* The pilot intervention was developed within the unique infrastructure of the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center (SKCCC), and the intervention design may therefore be neither feasible nor acceptable within other health care systems and patient populations, respectively
- *Strength:* The pilot intervention was translated from an established model of care (i.e., community health worker) with robust evidence in the scientific literature showing efficacy in addressing a variety of health conditions among populations that are underserved
- *Strength:* Our targeted sampling strategy, based upon assessing area deprivation index scores, will direct priority attention to populations residing in local zip codes with higher levels of poverty, substandard housing, and unemployment
- *Strength:* The study design and implementation plan emerged through partnership and collaboration between academic investigators and members from a long-established community advisory group (CAG)

BACKGROUND

Reliable health care utilization during the period between a cancer diagnosis and receiving initial treatment is crucial for facilitating favorable outcomes. Prolonging the start of treatment leads to poorer outcomes such as patient distress, worsening the progression of disease, and increasing the odds of mortality [1–3]. The average length of time for receiving initial cancer treatment has increased over the years, highlighting a public health concern warranting attention. Khorana et al. found a 38% increase in the time to initial cancer treatment following diagnosis across all cancer types in the United States between 2004-2013, using data from the National Cancer Database [2]. Additionally, patients who identified as Black experienced longer times to initial treatment compared to white counterparts across cancer types [2]. Although the exact cause of this increase in time to initial treatment following first cancer diagnosis is unclear, this delay is likely influenced by a combination of patient- and system-level factors [1,4].

Andersen’s behavioral model for health care utilization can guide investigators’ understanding of how patient- and system-level factors can affect timely access for initiating cancer treatments [5]. This model posits that patients' health care utilization is a function of joint factors across the environment, including the health care system, along with population- and individual-level patient characteristics that either enables or impedes certain health behaviors and use of health services [5]. This in turn is theorized to impact health outcomes adversely. Therefore, the model may inform novel program designs for reaching underserved demographics. This includes patients with low income and/or from minoritized racial backgrounds who may otherwise face higher risks for unfavorable outcomes due to structural and/or other social barriers associated with the environment and/or population characteristics [5].

In Andersen's behavioral model (Figure 1), *enabling resources* are key components for supporting and promoting timely treatment initiation and health care utilization by patients. One *enabling resource* for patients and their caregivers are community health worker (CHW) models of care, which commonly includes trained lay individuals or paraprofessionals who serve as important linkages between patient populations and health care systems [6,7]. Some examples of public health programs adapting CHW models include community-based interventions for improving breast and cervical cancer screenings among Korean American women [8], health service outreach for residents with history of stroke and hypertension in Harlem, New York [9], and providing a socially accessible hearing care program for older adults with hearing loss and low-to-moderate income in Baltimore, Maryland [10]. Evidence gathered through a prior systematic review of CHW-directed interventions reported treatment efficacy when compared with certain conventional models of health care and were cost-effective for managing certain health conditions [11]. Trained CHWs often share varied degrees of either language, culture, lived experiences, and/or geographic characteristics with their patient populations. The social concordance between CHWs and patient populations is a hallmark feature of CHW-directed programs, which can be optimized for providing patient-centered services [12]. Health systems, particularly ones with community-based partnerships like the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center (SKCCC) [13], can therefore also leverage CHW models as an *enabling resource* for addressing public health disparities [14].

The goal of the CHW navigation program is to focus on problem-solving in navigating the health care system. Prior studies of interventions focused on problem orientation and problem-solving with cancer patients and their caregivers have yielded evidence of promoting self-efficacy in managing care and in reducing stress [15–18]. From adapting Andersen's behavioral model [5], we theorize a relationship between the promotion of these outcomes and the activation of health behaviors that facilitate more timely treatment initiation. The problem-solving pilot intervention will be implemented at the systems-level and all cancer patients ages 18 years and older are eligible as prospective service users. The Johns Hopkins Hospital system (JHH) includes the SKCCC, which has a centralized call center for scheduling appointments regardless of cancer type and JHH provider team. Working through the SKCCC allows the intervention team to reach a broader range of new patients with various cancer diagnoses.

Our protocol manuscript describes a pilot program for assessing how the implementation of a CHW navigation program, focusing on problem-solving, will influence patients' treatment initiation and health care utilization for cancer treatment and care. We hypothesize that implementing the program would decrease the time leading up to the patient's initial oncology treatment visit following their first cancer diagnosis. Secondary hypotheses include observing an increase in the total number of oncology provider visits (e.g., patient retention), improvements in self-reported quality of life, and a decrease in the number of emergency department visits, hospitalizations, missed oncology appointments, reported stress, and premature mortality attributed to delaying care.

METHODS AND ANALYSIS

Study Design and Hypotheses

This pilot study will be a pre-test/post-test, hybrid effectiveness-implementation type-1 research design [19,20]. This design will primarily evaluate the effectiveness of the pilot CHW navigation program in facilitating patients' initiation of cancer treatment, health care utilization for oncology care, and perceived health status (patient stress and quality of life). Objectives of the pilot study include assessing the technical and administrative feasibility and acceptability of program implementation for informing a larger-scale intervention study in the future. Features of the current pilot program, such as recruitment strategies, adherence to protocol, and selected questionnaires will also be evaluated both for effective reach of the target population and for logistic feasibility. The following hypotheses will assess the impact of the pilot CHW navigation program:

1) The CHW navigation program will promote initiation of cancer treatment following the patient’s first cancer diagnosis.

    1a) The program will *decrease* time leading up to the initial oncology treatment visit.

2) The CHW navigation program will optimize patient’s health care utilization for recommended cancer care and treatment.

    2a) The program will *decrease* the number of emergency department visits, hospitalizations, and missed oncology appointments.

    2b) The program will *increase* the total number of provider-*recommended* oncology visits (mitigating health care *over*utilization).

3) The CHW navigation program will improve patients’ perceived health status.

    3a) The program will *decrease* patient-reported stress.

    3b) The program will *increase* patient-reported quality of life.

Study Setting and Sample

We will implement a CHW-directed navigation program among patients newly diagnosed with cancer. Health disparities within Baltimore City are well-documented with population life expectancies across local zip codes differing by as much as 20 years [21]. Patients will be consecutively sampled from nine zip codes in East Baltimore (21202, 21205, 21206, 21212, 21213, 21218, 21224, 21231, and 21239). These areas within East Baltimore show high incidences of cancer mortality and area deprivation index scores. Area deprivation index scores are calculated using sociodemographic characteristics of a neighborhood. Individuals living in neighborhoods with high area deprivation scores experience higher levels of poverty, substandard housing, unemployment, and lower levels of educational attainment. Areas with higher scores are also associated with higher mortality rates [22].

Patients will be eligible to participate if they present with their first cancer diagnosis and are over 18 years old. Patients must be seeking cancer care in the JHH system and have previously contacted the SKCCC for an appointment. Recruitment will follow a consecutive sampling strategy [23], and all eligible patients will be contacted by phone for study recruitment by a two-member CHW team affiliated with the SKCCC. Through the review of JHH Epic electronic medical health record data, there are approximately 2,155 SKCCC patients that may be eligible to participate in the study as a user of this health service.

Patient and Public Involvement in Research

The SKCCC prioritizes community engagement strategies for outreach and improving public trust in medical care [13]. The investigator team maintains a partnership with two community advisory groups (CAGs) coordinated by the SKCCC based in Baltimore City and Prince George's County (Maryland), respectively, that were established over ten years ago [24,25]. The CAGs meet monthly and form stakeholders from across the continuum of cancer care, including cancer survivors, caregivers, and representatives from local health departments, community-based organizations, and local faith-based communities. While CAG meetings are hosted by the SKCCC, their respective priorities and agendas are self-directed and self-managed by its membership. The CAGs contribute to research and practice through advising clinicians and researchers at SKCCC about patient and caregiver needs such as barriers in accessing care and priority outcomes [13]. Members are invited to weigh in on study designs, implementation plans, approaches in data analysis and interpretation, and the dissemination of study results.

Approximately three months prior to implementing the CHW navigator pilot program, investigators from the National Cancer Institute (NCI)-supported Johns Hopkins Center to Reduce Cancer Disparities (JHCRCD) began engaging the CAGs about the current program following members' reports of unique challenges in accessing care following the first cancer diagnosis. The CAGs also identified issues related to maintaining contact with a care team and a lack of transportation as barriers to care and contributors to increased stress levels, which directly informed the current study's priorities, outcomes of interest (stress and quality of life), and intervention development. The investigator team continues to meet regularly with the CAGs, who in turn also support recruitment efforts by promoting the study within their respective social networks.

Intervention: Community Health Worker (CHW) Navigation Program

The CHW navigation program will be provided to patients and caregivers to address cancer care-related problems and questions during the period between the patient's first cancer diagnosis and their initial treatment visit. The CHW navigation program adopts the C.O.P.E model to provide patients and caregivers with relevant guidance and expert information. The C.O.P.E. model includes four principles: Creativity, Optimism, Planning, and Expert information. It focuses on social problem-solving for both the patient and family caregiver(s) to optimize problem orientation and problem-solving [15,17,18]. The C.O.P.E. model has been widely documented in the scientific literature with oncology patients and their caregivers to assist with problem solving. The CHW navigation program incorporates these principles of C.O.P.E. to empower and engage patients and caregivers in their care. The implementation of the CHW navigation program is intended to influence patient health care utilization, as well as stress and quality of life.

The CHW team from SKCCC will contact eligible patients or their caregivers to assess patient interest in participating before obtaining informed consent. Upon enrolling, the CHWs will ask patients a series of varied questions dependent on whether the patient already received a confirmed diagnosis via biopsy report. For patients who do not have a biopsy-confirmed diagnosis on record, the CHW will facilitate scheduling a provider visit for ordering a biopsy, as needed, and direct patients to the appropriate JHH department for follow-up care (e.g., Surgery, Medical Oncology, or Radiation Therapy). The patient can leave the navigation program if they decide to seek cancer care elsewhere, or if the CHW is unable to meet the patient’s specific needs at that time.

Alternatively, CHWs will focus on scheduling the initial appointment with oncology for patients who have a biopsy-confirmed diagnosis on record. During a call, the CHW will identify any barriers inhibiting the patient from scheduling their first oncology visit. This may include logistical barriers, such as a lack of transportation, childcare, or understanding how to use MyChart, an online personal health record system used to schedule appointments, view medications and test results, and connect with providers. The CHW may also identify psycho-emotional barriers, such as fear, mistrust, or a lack of support. After the CHW identifies these barriers, they will connect the patient with the appropriate online community resources from Johns Hopkins Electronic Resource databases. The CHW may initiate discussions for scheduling either an in-home or office visit for the patient’s initial oncology treatment. CHWs will anticipate and prepare for multiple phone calls with patients presenting with more complex needs to provide sufficient information and navigation support.

Outcome of Interests

The primary outcome is time to the initial treatment visit following a cancer diagnosis. Secondary outcome variables include health care utilization at three- and six-months after the completion of the program, cost of care, number of problems resolved, number of community resources used, stress, and quality of life. The accessibility and feasibility of the program will be assessed by the established CAGs through semi-structured discussions. Members from the

CAGs vetted all proposed questionnaires and procedures before receiving formal approval from a research ethics review board and the project sponsor. See Table 1 for specific short- and long-term outcome variables.

Table 1. Short- and Long-Term Outcome Variables.

	Variable	**Measurement**
Short-Term Outcome$_1$	Cancer Related-Problem	Problem-Checklist (25-item)
	Stress	Chronic Illness Distress Scale (7-item)
	Quality of Life	Satisfaction with Life Domains (16-item)
Long-term Outcome$_2$	Time to first oncology treatment visit $_3$	Time to first oncology treatment visit following patient's cancer-confirmed biopsy
	Healthcare Utilization$_3$	Number of ED visits Number of hospitalizations Length of hospital stay Mortality Number of oncology visits (telehealth/in-person) Number of missed oncology visits
	Cost of Care$_3$	Pharmacy charges Radiology charges

$_1$During CHW Navigation Program Contact; $_2$Three-Month and 6-Month post-program; $_3$Data provided from Epic (electronic health record)

Instruments

The time to initial oncology treatment visit and health care utilization data will be obtained from Epic, an electronic medical record database. Time to initial oncology treatment visit is defined as the time from the patient's biopsy-confirmed diagnosis to their first oncology treatment. Health care utilization encompasses the number of oncology visits (via telehealth or in-person), missed oncology visits, emergency department (ED) visits, hospitalizations and length of hospital stay, and patient mortality. The cost of care (e.g., pharmacy and radiology charges) will also be measured with data from Epic.

The Problem-Checklist is a 25-item inventory of problems cancer patients have reported during and after diagnosis and treatment. The Problem-Checklist will assist in identifying problems to focus on during the intervention. To measure quality of life, the patient will complete the Satisfaction with Life Domains Scale (16-items). The scale uses a seven-point Likert rating system, ranging from 1 (most satisfied) to 7 (most dissatisfied). This scale was previously used with breast cancer survivors and patients who received bone marrow transplants and were positively received by both patient populations [26,27]. The Chronic Illness Distress scale will measure stress. This scale is a 16-item, four-point Likert scale ranging from *not upset* to *very upset*. These brief questionnaires will be completed upon entry into the program (i.e., baseline) with interim follow-up data collected at three-months and the final time point at six-months post-intervention.

Patient sociodemographic information will be collected using a Patient Demographics Questionnaire. This questionnaire includes items about age, marital status, race/ethnicity, education, employment status, annual household income, cancer diagnosis, and time of diagnosis.

Data Collection

Short-term outcome variables will be collected by CHW team members during the first series of phone calls with the participant. CHWs will review each questionnaire with the participant and record their responses. Each CHW will also maintain a journal of interactions with the participant, detailing the participant’s problem, resources used to address the problem, who they reached and engaged (patient or informal/formal caregiver), and the number of phone calls made. All data will be secured in accordance with university policies for upholding study confidentiality. Long-term outcome variables will be collected through Epic and stored in REDCap. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources [28,29]. For assessing the low-cost feature of the CHW navigation program, our team will document the resources expended during implementation such as staffing hours and costs of communication resources. We will also document the number of patients served by the program to demonstrate our reach.

Analytic Plan

We will collect all measures (Table 1) before and after implementing the CHW navigation program. CHWs will collect information by phone through the Problem Checklist, Chronic Illness Distress scale, and Satisfaction with Life Domains scale before providing guidance on cancer-related problem(s). Additionally, we will assess the time to the initial oncology treatment visit and health care utilization through evaluating data from Epic at three- and six-months following the program. Data analyses will occur at each timepoint of data collection (baseline and post-program; immediate, three-months, and six-months). Univariate analyses will be completed to describe the sample. Bivariate analyses will be completed to understand relationships between receipt of the program and all outcome variables. We will use independent t-tests to assess the program's impact on participant stress, quality of life, number of problems reported, and health care utilization. We will use repeated paired t-tests (under a Bonferroni correction) on the following: average pre-test to each post-test data collection point for distress, severity of symptoms, and problem-solving behaviors. Additional paired t-tests will be conducted to determine if there is a difference in the same variables over time.

ETHICS AND DISSEMINATION

This study completed an ethical review through the Johns Hopkins School of Medicine's institutional review board (IRB00160610) and received initial approval on August 1, 2019. At the time of this writing (2022), the current protocol is approved through July 6, 2023, coinciding with the projected study conclusion after confronting implementation delays due to local public health guidelines introduced during the COVID-19/SARS-CoV-2 pandemic which restricted research and clinical activities at SKCCC. Discussions surrounding the study's dissemination plans are ongoing through regular meetings between members of the investigator team (JHCRCD) and members of the public (CAGs). The JHCRCD and CAGs together will also be collaborating with other entities such as the Johns Hopkins Institute for Clinical and Translational Research and the Johns Hopkins Center for Health Equity (formerly the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities) [30,31], who offer additional expertise drawn from experience in forging academic-community partnerships for study conduct and disseminating findings [32].

DISCUSSION

We will implement a pilot CHW navigation program to support patient populations in Baltimore City who face higher risk of delaying initial cancer treatment visits or becoming lost to follow-up throughout the care continuum. Our sampling strategy targets residents of select urban zip codes with high area deprivation index scores where patients are more likely to confront barriers to timely health care engagement attributed to respective social determinants of health. The CHW will serve as a linkage between patients newly diagnosed with cancer and their oncology provider team at the JHH. As an *enabling resource* for supporting cancer care utilization by patient populations facing higher risks for adverse outcomes, a CHW navigation program also supports pathways for promoting health equity. Like other CHW models of care, the health worker does not directly provide medical consultation nor primary care. Rather, they are trained to support patients' problem-solving skills for navigating their health care, connect patients to relevant resources, and help coordinate care with the goal of reducing time to initiating treatment. Since health care utilization during the time between first diagnosis and initial treatment represents a critical period that can significantly modify health outcomes, reducing this time improves the prospects of survivorship and experiencing a better quality of life.

There will be several limitations worth noting in implementing this program. Firstly, there will be no exclusion criterion based on cancer type. This results in a heterogeneous sample of patients with varying needs; some may require several contacts with a CHW to sense adequate support while others may only require one point of contact. Secondly, only patients who have previously contacted the SKCCC will be reached, thus introducing population selection bias to consider. Inherent structural factors that impede access to health systems such as the SKCCC should also be considered when designing programs aiming to address barriers to cancer care. Furthermore, our program is connecting patients who are still early in their cancer care trajectory, and therefore may not yet be knowledgeable enough to articulate their complete needs to the CHW. However, engagements with a CHW navigator still offer an initial point of linkage to resources that patients and caregivers may access during relevant periods later in their care trajectory. Finally, the program will be operating within the context of the JHH system and therefore other institutions with different infrastructures may benefit from considering another implementation strategy.

Our CHW navigation program represents an innovative approach to address disparities early in cancer care and supports the odds of survivorship by leveraging a model commonly used for reaching underserved patient populations [33]. The role of the CHW has proliferated due to demonstrated effectiveness in community outreach, social support, informal counseling, and health education [34]. The paraprofessional workforce is associated with improved care access and reduced health care costs [6,35], particularly among socially minoritized populations [36,37]. While the CHW navigation program will be based within JHH, conducting outreach to patients who are not *yet* fully integrated within the health care system presents another unique advantage. Patients usually need to be completely onboarded before being eligible to receive navigation services by either a trained CHW or staff nurse. Our hospital based CHW, who may also be perceived as more approachable than health care staff by patients, serves as a linkage with patients in the Baltimore community *before* they spend the additional time usually needed to integrate with a health care team. Waiting for patients to be fully onboarded before receiving navigation services may otherwise risk further delaying initial treatment. The CHW navigator therefore operates within a “transitional space” for patients in their care trajectory when they may face higher risk of becoming lost to follow-up due to barriers in health care systems, including those attributable to ongoing legacies of structural racism and discrimination. A CHW navigator may also provide further assurance for a medical provider team who would know that their patients can remain better connected to vital health care through the CHW-directed service. Finally, a CHW navigation program may also represent a lower-cost approach [6,35] in reaching underserved demographics with cancer diagnoses. Resources for operating such a program include properly allocating staff hours (including time for CHW training, program delivery, and continuing education as needed), adequate workspaces, and communications equipment. Taken together, we propose our CHW navigation program for cancer care as a cost-effective approach to facilitate better outcomes for both patients, their caregivers, and the health care system.

We will pilot our novel CHW navigation program and evaluate its feasibility and acceptability among populations with recent cancer diagnoses who are traditionally underserved by health care systems in Baltimore City. Our program represents an *enabling resource* [5] to support health care utilization for patients and their caregivers during a critical period when initiating treatment by oncology in a timely manner is crucial for favorable outcomes. Our program protocol describes key guiding frameworks, program features, and an analytic plan that we aim to follow for implementation.

Declarations

Competing Interests

The authors declare that they have no competing interests.

Funding

This work was supported by the Merck Foundations Alliance to Advance Patient-Centered Cancer Care after a competitive call for Alliance projects with program oversight from a designated National Program Office within the University of Michigan School of Nursing (grant number 19-9714). The Merck Foundations Alliance provided funding for implementing project operations. JJS is supported in part by the National Institute on Aging/National Institutes of Health (grant number F31AG071353) and the Johns Hopkins Cochlear Center for Hearing and Public Health which is supported in part by a philanthropic gift from Cochlear, Ltd. The funders listed above have no role in both the conduct and outcomes of the study.

Authors' Contributions

All authors contributed to the conceptualization of this manuscript. JJS and EP drafted the manuscript as co-first authors and all other authors contributed substantial feedback and writing for revisions, including a CHW from SKCCC (OS). AD and JZ advised the manuscript's development as co-senior authors and principal investigator (AD) of the grant awarded by the Merck Foundation.

Acknowledgments

The authors would like to acknowledge the support of the Merck Foundation in this program of research. The authors would also like to acknowledge Dr. Debra Roter and Ms. Marielle (Mari) Bugayong for their guidance and expertise. Finally, we would also like to express our deepest gratitude to the members of the SKCCC's community advisory groups (CAGs) without whom the development of this program would not be possible.

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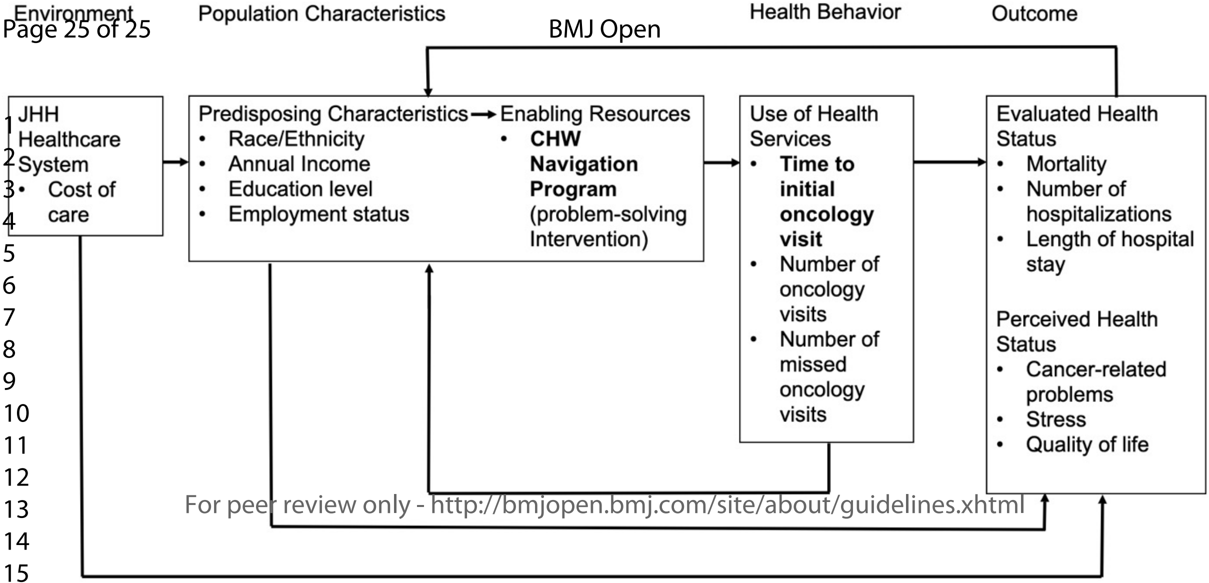
FIGURE LEGEND

Figure 1. Adapted Andersen's behavioral model for health care utilization. The CHW navigation program serves as an *enabling resource* for promoting appointment-keeping and follow-up (i.e., retention). In the model, the time to initial oncology treatment is defined as the time between the patient's first cancer diagnosis and the start of cancer treatment. Furthermore, health care utilization encompasses the provider's *recommended* use of health care services, and the number of oncology visits, number of missed oncology visits, mortality, number of hospitalizations, and length of hospital stay are used as a proxy to measure this concept.


Environment
Population Characteristics
Health Behavior
Outcome
JHH Healthcare System
• Cost of care
Predisposing Characteristics
• Race/Ethnicity
• Annual Income
• Education level
• Employment status
Enabling Resources
• CHW Navigation Program (problem-solving Intervention)
Use of Health Services
• Time to initial oncology visit
• Number of oncology visits
• Number of missed oncology visits
Evaluated Health Status
• Mortality
• Number of hospitalizations
• Length of hospital stay
Perceived Health Status
• Cancer-related problems
• Stress
• Quality of life

BMJ Open

Improving cancer care for underserved populations in an academic and community practice setting: protocol for a community health worker pilot navigation program

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-067270.R1
Article Type:	Protocol
Date Submitted by the Author:	25-Oct-2022
Complete List of Authors:	Suen, Jonathan; Johns Hopkins University, School of Nursing; Johns Hopkins University Bloomberg School of Public Health Parrillo, Elaina; Johns Hopkins University, School of Nursing Hassoon, Ahmed; Johns Hopkins Medicine; Johns Hopkins University Bloomberg School of Public Health Peairs, Kimberly ; Johns Hopkins Medicine Sidney Kimmel Comprehensive Cancer Center; Johns Hopkins Medicine Stanford, Olivia; Johns Hopkins Medicine Sidney Kimmel Comprehensive Cancer Center; Johns Hopkins Medicine Wenzel, Jennifer; Johns Hopkins University, School of Nursing; Johns Hopkins Medicine Sidney Kimmel Comprehensive Cancer Center Zabora, James; Johns Hopkins Medicine Dobs, Adrian; Johns Hopkins Medicine
Primary Subject Heading:	Oncology
Secondary Subject Heading:	Health services research, Public health
Keywords:	ONCOLOGY, Adult oncology < ONCOLOGY, PUBLIC HEALTH

Improving cancer care for underserved populations in an academic and community practice setting: protocol for a community health worker pilot navigation program

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Word Count: 3,986 (4,000 max)

ABSTRACT

Introduction: Delaying cancer treatment following diagnosis impacts health outcomes, including increasing patient distress and odds of mortality. Interventions to promote timely health care engagement may decrease patient-reported stress and improve quality-of-life. Community health workers (CHWs) represent an *enabling resource* for reducing delays in attending initial oncology treatment visits. As part of an ongoing program evaluation coordinated by the Merck Foundation, we will implement a pilot navigation program comprising CHW-conducted needs assessments for supporting patients and their caregivers. We aim to investigate (1) the program's influence on patients' health care utilization within the period between their first diagnosis to initial treatment visit, and (2) the logistic feasibility and acceptability of program implementation.

Methods and analysis: We will employ a hybrid implementation design to introduce the CHW navigation program at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center. CHW team members will use a consecutive sampling approach. Participants will complete the Problem-Checklist, Chronic Illness Distress Scale, and the Satisfaction with Life Domains instruments. CHWs will provide tailored guidance by sharing information available on the Johns Hopkins Electronic Resource databases. The investigators will evaluate patients' time to initial oncology treatment and health care utilization through reviewing electronic medical records at three- and six-months post-intervention. Bivariate analyses will be completed to evaluate the relationships between receiving the program and all outcome measures.

Ethics and dissemination: This study's protocol was approved by the Johns Hopkins School of Medicine's institutional review board (IRB00160610). Informed consent will be obtained by phone by the CHW navigator. Dissemination planning is ongoing through regular meetings between members of the investigator team and public members of two community advisory groups (CAGs). Study plans include collaborating with other experts from the Johns Hopkins Institute for Clinical and Translational Research and the Johns Hopkins Center for Health Equity for ideating dissemination strategies.

Keywords: cancer, community health workers, health equity, patient navigation, quality of life

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The pilot intervention was translated from an established model of care (i.e., community health worker) with robust evidence in the scientific literature showing efficacy in addressing a variety of health conditions among populations that are underserved.
- Our targeted sampling strategy, based upon assessing area deprivation index scores, directed priority attention to populations residing in local zip codes with higher levels of poverty, substandard housing, and unemployment.
- The study design and implementation plan emerged through partnership and collaboration between academic investigators and members from a long-established community advisory group (CAG).
- The target sample will be a heterogeneous population given the lack of an exclusion criterion based on cancer type.
- The pilot intervention was developed within the unique infrastructure of the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center (SKCCC), and the intervention design may therefore be neither feasible nor acceptable within other health care systems and patient populations, respectively.

INTRODUCTION

Reliable health care utilization during the period between a cancer diagnosis and receiving initial treatment is crucial for facilitating favorable outcomes. Prolonging the start of treatment leads to poorer outcomes such as patient distress, worsening the progression of disease, and increasing the odds of mortality [1–3]. The average length of time for receiving initial cancer treatment has increased over time, highlighting a public health concern warranting attention. Khorana et al. found a 38% increase in the time to initial cancer treatment following diagnosis across all cancer types in the United States between 2004-2013, using the data from the National Cancer Database [2]. Additionally, patients who identified as Black had an increased time to initial treatment compared to white counterparts across cancer types [2]. Although the exact cause of this increase in time to initial treatment following first cancer diagnosis is unclear, this delay is likely influenced by a combination of patient- and system-level factors [1,4].

Andersen's behavioral model for health care utilization can guide investigators' understanding of how patient- and system-level factors can affect timely access for initiating cancer treatments [5]. This model posits that patients' health care utilization is a function of combined factors across the environment, including the health care system, along with population- and individual-level patient characteristics that either enables or impedes certain health behaviors and use of health services [5]. This in turn is theorized to impact health outcomes adversely. Therefore, the model may inform novel program designs for reaching underserved demographics, such as patients with low income and/or from minoritized racial backgrounds, who may otherwise face higher risks for unfavorable outcomes due to structural and/or other social barriers associated with the environment and/or population characteristics [5].

In Andersen's behavioral model (Figure 1), *enabling resources* are key components for supporting and promoting timely treatment initiation and health care utilization by patients. One *enabling resource* for patients and their caregivers are community health worker (CHW) models of care, which commonly comprises trained lay individuals or paraprofessionals who serve as important linkages between patient populations and health care systems [6,7]. Some examples of public health programs adapting CHW models include community-based interventions for improving breast and cervical cancer screenings among Korean American women [8], health service outreach for residents with history of stroke and hypertension in Harlem, New York (USA) [9], and providing a socially accessible hearing care program for older adults with hearing loss and low-to-moderate income in Baltimore, Maryland (USA) [10]. Evidence gathered through a systematic review of CHW-directed interventions reported treatment efficacy when compared with certain conventional models of health care and were cost-effective for managing certain health conditions [11]. Trained CHWs often share varied degrees of either language, culture, lived experiences, and/or geographic characteristics with their patient populations. The social concordance between CHWs and patient populations is a hallmark feature of CHW-directed programs, which can be optimized for providing patient-centered services [12]. Health systems, particularly ones with community-based partnerships like the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center (SKCCC) [13], can therefore also leverage CHW models as an *enabling resource* for addressing public health disparities [14].

The goal of the CHW navigation program involves conducting a needs assessment and focusing on problem-solving for navigating the health care system. Prior studies of interventions focused on problem orientation and problem-solving with cancer patients and their caregivers have yielded evidence of promoting self-efficacy in managing care and in reducing stress [15–18]. From adapting Andersen's behavioral model [5], we theorize a relationship between the activation of respective health behaviors identified through a needs assessment and more timely treatment initiation. The pilot program will be implemented at the systems-level and all cancer patients ages 18 years and older are eligible as prospective service users. The Johns

Hopkins Hospital system (JHH) includes the SKCCC, which has a centralized call center for scheduling appointments regardless of cancer type and JHH provider team. Working through the SKCCC allows the intervention team to reach a broader range of new patients with various cancer diagnoses.

Our protocol manuscript describes a pilot program featuring a CHW-directed needs assessment and health care navigation services. We will assess the program’s influence on patients’ treatment initiation and health care utilization, as well as the feasibility of program implementation. We hypothesized that implementing the program would decrease the time leading up to the patient’s initial oncology treatment visit following their first cancer diagnosis. Secondary hypotheses include observing an increase in the total number of oncology provider visits (e.g., patient retention), improvements in self-reported quality of life, and a decrease in the number of emergency department visits, hospitalizations, missed oncology appointments, reported stress, and premature mortality attributed to delaying care.

METHODS AND ANALYSIS

Study design and hypotheses

This pilot study will be a pre-test/post-test, hybrid effectiveness-implementation type-1 research design [19,20]. This design will evaluate the effectiveness of the pilot CHW navigation program in facilitating patients' initiation of cancer treatment, health care utilization for oncology care, and perceived health status (patient stress and quality of life). Additional objectives include assessing the feasibility of technical and administrative processes in implementing such a program (e.g., recruitment using electronic medical record data, number of staff personnel needed, etc.), as well as the acceptability of program for informing a larger-scale intervention study in the future. Feasibility and acceptability are key features to consider in addition to effectiveness of the program to understand how the intervention may be incorporated into practice at the SKCCC [21].

The following hypotheses will assess the impact of the pilot CHW navigation program:

1) The CHW navigation program will promote timely initiation of cancer treatment following the patient's first cancer diagnosis.

1a) The program will *decrease* time leading up to the initial oncology treatment visit.

2) The CHW navigation program will facilitate patient's health care utilization for recommended cancer care and treatment.

2a) The program will *decrease* the number of emergency department visits, hospitalizations, and missed oncology appointments

2b) The program will *increase* the total number of provider-recommended oncology visits (mitigating health care overutilization).

3) The CHW navigation program will improve patients' perceived health status.

3a) The program will *decrease* patient-reported stress.

3b) The program will *increase* patient-reported quality of life.

This protocol previously underwent a scientific peer review by subject matter experts with support from the Merck Foundation (proposal #19-9714). The SKCCC-based program is part of a broader network of initiatives across six cancer centers coordinated through the Alliance to Advance Patient-Centered Cancer Care, henceforth referred to as the "Alliance" [22].

Study setting and sample

We will implement a CHW-directed needs assessment and navigation program among patients newly diagnosed with cancer. Health disparities within Baltimore City are well-documented with population life expectancies across local zip codes differing by as much as 20 years [23]. Patients will be consecutively sampled from nine zip codes in East Baltimore (21202, 21205, 21206, 21212, 21213, 21218, 21224, 21231, and 21239). These areas within East Baltimore show high incidences of cancer mortality and area deprivation index (ADI) scores. Rather than relying solely on race or ethnicity as proxy indicators of social factors associated with poorer health outcomes, we will utilize ADI to incorporate a more holistic approach (i.e., incorporating social and structural factors) in reaching underserved demographics. Area deprivation index scores are calculated using sociodemographic characteristics of a neighborhood. Individuals living in neighborhoods with high ADI scores experience higher levels of poverty, mortality rates, substandard housing, unemployment, and lower levels of educational attainment [22]. Patients living in areas with higher ADIs are also more likely to have lower levels of health literacy, as literacy levels are associated with the social factors used to calculate ADI [24].

Patients will be eligible to participate if they present with their first cancer diagnosis and are over 18 years old. Patients must be seeking cancer care in the JHH system and have previously contacted the SKCCC for an appointment. Recruitment will follow a consecutive sampling strategy [25], and all eligible patients will be contacted by phone for study recruitment by a two-member CHW team affiliated with the SKCCC. Through a review of the JHH Epic electronic medical health record data, there are approximately 2,155 SKCCC patients over the age of 18 with a first-time cancer diagnosis who meet inclusion criteria for recruitment.

Patient and public involvement

The SKCCC prioritizes community engagement strategies for outreach and improving public trust in medical care [13]. The investigator team maintains a partnership with two community advisory groups (CAGs) coordinated by the SKCCC based in Baltimore City and Prince

George's County (Maryland, USA), respectively, that were established over ten years ago [26,27]. The CAGs meet monthly and comprise stakeholders from across the continuum of cancer care, including cancer survivors, caregivers, and representatives from local health departments, community-based organizations, and local faith-based communities. While CAG meetings are hosted by the SKCCC, their respective priorities and agendas are self-directed and self-managed by its membership. The CAGs contribute to research and practice through advising clinicians and researchers at SKCCC about patient and caregiver priorities such as barriers in accessing care and priority outcomes [13]. Members are invited to weigh in on study designs, implementation plans, approaches in data analysis and interpretation, and the dissemination of study results.

Approximately three months prior to implementing the CHW navigator pilot program, investigators from the National Cancer Institute (NCI)-supported Johns Hopkins Center to Reduce Cancer Disparities (JHCRCD) began engaging the CAGs about the current program following members' reports of unique challenges in accessing care following the first cancer diagnosis. The CAGs also identified issues related to maintaining contact with a care team and a lack of transportation as barriers to care and contributors to increased stress levels, which directly informed the current study's priorities, outcomes-of-interest (stress and quality-of-life), and intervention development. The investigator team continues to meet regularly with the CAGs, who in turn also support recruitment efforts by promoting the study within their respective social networks.

Intervention: community health worker (CHW) navigation program

The CHW navigation program will be provided to patients and caregivers to address cancer care-related problems during the period between first diagnosis and the initial treatment visit. The CHW navigation program adopts the C.O.P.E model to provide patients and caregivers with guidance and expert information. The C.O.P.E. model includes four principles: Creativity, Optimism, Planning, and Expert information. It focuses on social problem-solving for both the patient and family caregiver(s) to optimize problem orientation and problem-solving [15,17,18]. The C.O.P.E. model has been widely documented in the scientific literature with oncology patients and their caregivers to assist with problem-solving. The CHW navigation program incorporates these principles of C.O.P.E. to empower and engage patients and caregivers in their care. The implementation of the CHW navigation program is intended to influence patients' health care utilization, as well as stress and quality of life.

The CHW team from SKCCC will contact eligible patients or their caregivers to assess interests in participating before obtaining informed consent. Upon enrolling, the CHWs will ask patients a series of scripted questions as a needs assessment. The questions asked will be tailored to whether the patient already received a confirmed diagnosis via biopsy report. This allows a more flexible approach for the delivery of the program and helps tailor the intervention accordingly for the respective needs of different patients and/or caregivers. This flexibility was prioritized by the Alliance to accommodate the unique infrastructures and capacities of the six NCI-designated cancer centers within the project's network [22], and represents an important feature of many complex interventions [21,28,29]. For patients who do not have a biopsy-confirmed diagnosis on record, the CHW will facilitate scheduling a biopsy visit, as needed, and direct patients to the appropriate JHH department for follow-up care (e.g., Surgery, Medical Oncology, or Radiation Therapy). The patient can leave the navigation program if they decide to seek cancer care elsewhere, or if the CHW is unable to meet the patient's specific needs at that time. All points of contact with patients and/or caregivers throughout the program will be documented as encounter notes by the CHW navigators.

Alternatively, CHWs will focus on scheduling the initial appointment with oncology for patients who have a biopsy-confirmed diagnosis on record. During a call, the CHW will identify any barriers inhibiting the patient from scheduling their first oncology visit. This may include logistical barriers, such as a lack of transportation, childcare, or understanding how to use MyChart, an online personal health record system used to schedule appointments, view medications and test results, and connect with providers. The CHW may also identify psycho-emotional barriers, such as fear, mistrust, or a lack of support. After the CHW identifies these barriers, they will connect the patient with the appropriate online community resources from Johns Hopkins Electronic Resource databases. The CHW may initiate discussions for scheduling either an in-home or office visit for the patient's initial oncology treatment, if appropriate. CHWs will anticipate and prepare for multiple phone calls with patients who have more complex needs to provide sufficient information and navigation support.

Outcome of interests

The primary outcome is time to the initial treatment visit following a cancer diagnosis. Secondary outcome variables include health care utilization at three- and six-months after the completion of the program, cost of care, number of problems resolved, number of community resources used, stress, and quality of life (QOL). The acceptability of the program by patient and caregiver populations will be assessed by the established CAGs through semi-structured discussions hosted by the investigator team. Members from the CAGs vetted all proposed questionnaires and procedures before receiving formal approval from a research ethics review board and the project sponsor. See Table 1 for specific short- and long-term outcome variables.

Table 1. Short- and long-term outcome variables

	Variable	**Measurement**
Short-term Outcomes$_1$	Cancer-related problem Stress Quality of Life	Problem-Checklist (25-item) Chronic Illness Distress Scale (7-item) Satisfaction with Life Domains (16-item)

Long-term outcomes$_2$	Time to first oncology treatment visit $_3$	Time to first oncology treatment visit following patient's cancer-confirmed biopsy
	Healthcare utilization$_3$	Number of ED visits Number of hospitalizations Length of hospital stay Mortality Number of oncology visits (telehealth/in-person) Number of missed oncology visits
	Cost of care$_3$	Pharmacy charges Radiology charges
$_1$During CHW Navigation Program Contact; $_2$Three-Month and 6-Month post-program; $_3$Data provided from Epic (electronic health record)		

Instruments

The time to initial oncology treatment visit and health care utilization data will be obtained from Epic, an electronic medical record database. Time to initial oncology treatment visit is defined as the time from the patient's biopsy-confirmed diagnosis to their first oncology treatment. Health care utilization encompasses the number of oncology visits (via telehealth or in-person), missed oncology visits, emergency department (ED) visits, hospitalizations and length of hospital stay, and patient mortality. The cost of care (e.g., pharmacy and radiology charges) will also be tracked through reviewing data from Epic.

The current study will utilize the following instruments as directed by the Alliance for harmonizing outcomes across the six cancer centers [22]. The Problem-Checklist is a 25-item inventory of problems cancer patients have reported during and after diagnosis and treatment. The Problem-Checklist will assist in identifying problems to focus on during the intervention. To measure quality of life, the patient will complete the Satisfaction with Life Domains Scale, a 16-item scale. The scale uses a seven-point Likert rating system, ranging from 1 (most satisfied) to 7 (most dissatisfied). This scale was previously used with breast cancer survivors and patients who received bone marrow transplants and were positively received by both patient populations [30,31]. The Chronic Illness Distress scale will measure stress. This scale is a 16-item, four-point Likert scale ranging from *not upset* to *very upset*. These brief questionnaires will be completed upon entry into the program with interim follow-up data collected at three- and six-months.

Patient sociodemographic information will be collected using a Patient Demographics Questionnaire. This questionnaire includes items about age, marital status, race/ethnicity, education, employment status, annual household income, cancer diagnosis, and time of diagnosis.

Data collection

Short-term outcome variables will be collected by CHW team members during the first series of phone calls with the participant. CHWs will review each questionnaire with the participant and record their responses. Each CHW will also maintain a journal of interactions (encounter notes) with participants, detailing the participant's problem, resources used to address the problem, who they spoke with (patient or informal/formal caregiver), and the number of phone calls made. All data will be secured in accordance with university policies for upholding study confidentiality. Long-term outcome variables will be collected through Epic and stored in REDCap. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources [32,33]. For assessing the low-cost feature of the CHW navigation program, our team will document the resources expended during implementation such as staffing hours and costs of communication resources. We will also document the number of patients served by the program to demonstrate our reach.

Analytic plan

We will collect all measures (Table 1) before and after implementation of the CHW Navigation Program. CHWs will collect information by phone through the Problem Checklist, Chronic Illness Distress scale, and Satisfaction with Life Domains scale before providing guidance on cancer-related problem(s). Additionally, we will assess the time to the initial oncology treatment visit and health care utilization through evaluating data from Epic at three- and six-months following the program. Data analyses will occur at each timepoint of data collection (baseline and post-program; immediate, three-months, and six-months). Univariate analyses will be completed to describe the sample. Bivariate analyses will be completed to understand relationships between receipt of the program and all outcome variables. We will use independent t-tests to assess the program's impact on participant stress, quality of life, number of problems reported, and health care utilization. We will use repeated paired t-tests (under a Bonferroni correction) on the following: average pre-test to each post-test data collection point for distress, severity of symptoms, and problem-solving behaviors. Additional paired t-tests will be conducted to determine if there is a difference in the same variables over time.

ETHICS AND DISSEMINATION

This study completed an ethical review through the Johns Hopkins School of Medicine's institutional review board (IRB00160610) and received initial approval on August 1, 2019. This study includes an IRB-approved informed consent process where we will obtain oral consent by phone from each participant prior to enrollment in the program. At the time of this writing (2022), the current protocol is approved through July 6, 2023, coinciding with the projected study conclusion after confronting implementation delays due to local public health guidelines implemented during the COVID-19/SARS-CoV-2 pandemic which restricted research and clinical activities at SKCCC. Discussions surrounding the study's dissemination plans are ongoing through regular meetings between members of the investigator team (JHCRCD) and members of the public (CAGs). The JHCRCD and CAGs together will also be collaborating with other entities such as the Johns Hopkins Institute for Clinical and Translational Research and the Johns Hopkins Center for Health Equity (formerly the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities) [34,35], who offer additional expertise drawn from experience in forging academic-community partnerships for study conduct and disseminating findings [36].

DISCUSSION

We will implement a pilot CHW navigation program to support patient populations in Baltimore who face higher risk of delaying initial cancer treatment visits or becoming lost to follow-up throughout the care continuum. Our sampling strategy targets residents of select urban zip codes with high ADI scores where patients are more likely to confront barriers to timely health care engagement [37] and are less likely to participate in research studies [38], attributed to respective social determinants of health. CHWs have been shown to be effective in improving access and engagement with health care in underserved populations [6,39] and are well positioned to support cancer patients in reducing the time to initial cancer treatment.

The CHW will serve as a linkage between patients newly diagnosed with cancer and their oncology provider team at the JHH. As an *enabling resource* for supporting cancer care utilization by patient populations facing higher risks for adverse outcomes, a CHW navigation program also supports pathways for promoting health equity. Like other CHW models of care, the health worker does not directly provide medical consultation nor primary care. Rather, they are trained to identify patients' and caregivers' needs and support problem-solving skills for navigating their health care. The CHWs also provide support by connecting patients to relevant resources and help coordinate care with the goal of reducing time to initiating treatment. Since health care utilization during the time between first diagnosis and initial treatment represents a critical period that can significantly modify health outcomes, reducing this time improves the prospects of survivorship and experiencing a better quality of life.

There will be several limitations worth noting in implementing this program. Firstly, there will be no exclusion criterion based on cancer type. This results in a heterogeneous sample of patients with varying needs; some may require several contacts with a CHW to sense adequate support while others may only require one point of contact. Secondly, only patients who have previously contacted the SKCCC will be reached, thus introducing population selection bias to consider. Inherent structural factors that impede access to health systems such as the SKCCC should also be considered when designing programs aiming to address barriers to cancer care. Furthermore, our program is connecting patients who are still early in their cancer care trajectory, and therefore may not yet be knowledgeable enough to articulate their complete needs to the CHW. However, engagements with a CHW navigator still offer an initial point of linkage to resources that patients and caregivers may access during relevant periods later in their care trajectory. Finally, the program will be operating within the context of the JHH system and therefore other institutions with different infrastructures may benefit from considering another implementation strategy.

Our CHW navigation program represents an innovative approach to address disparities early in cancer care and supports the odds of survivorship by leveraging a model commonly used for reaching underserved patient populations [40]. The role of the CHW has proliferated due to demonstrated effectiveness in community outreach, social support, informal counseling, and health education [41]. The paraprofessional workforce is associated with improved care access and reduced health care costs [6,42], particularly among socially minoritized populations [43,44]. While the CHW navigation program will be based within JHH, conducting outreach to patients who are not *yet* fully integrated within the health care system presents another unique advantage. Patients usually need to be completely onboarded before being eligible to receive navigation services by either a trained CHW or staff nurse. Our hospital based CHW, who may also be perceived as more approachable than health care providers by patients, serves as a linkage with patients in the Baltimore community *before* they spend the additional time usually needed for integrating with a health care team. Waiting for patients to be fully onboarded before receiving navigation services may otherwise risk further delaying initial treatment. The CHW navigator therefore operates within a "transitional space" for patients in their care trajectory when they may face higher risk of becoming lost to follow-up due to barriers in health care systems, including those attributable to legacies of structural racism. A CHW navigator may also provide further assurance for a medical provider team who would know that their patients can remain better connected to vital health care through the CHW-directed service. Finally, a CHW navigation program may also represent a lower-cost approach [6,42] in reaching underserved demographics with cancer diagnoses. Resources for operating such a program include properly allocating staff hours (including time for CHW training, program delivery, and continuing education as needed), adequate workspaces, and communications equipment. Taken together, we propose our CHW navigation program for cancer care as a cost-effective approach to facilitate better outcomes for both patients, their caregivers, and the health care system.

We will pilot our novel CHW navigation program and evaluate its logistic feasibility and acceptability among populations with recent cancer diagnoses who are traditionally underserved by health care systems in Baltimore City. Our program represents an *enabling resource* [5] to support health care utilization for patients and their caregivers during a critical period when initiating treatment by oncology in a timely manner is crucial for favorable outcomes. Our program protocol describes key guiding frameworks, program features, and an analytic plan that we aim to follow for implementation.

Declarations

Competing interests

The authors declare that they have no competing interests.

Funding

This work was coordinated through the Alliance to Advance Patient-Centered Cancer Care, with support from the Merck Foundation (proposal #19-9714), after a competitive call for Alliance-affiliated projects with program oversight from a designated National Program Office within the University of Michigan School of Nursing. JJS is supported in part by the National Institute on Aging/National Institutes of Health (F31AG071353) and the Johns Hopkins Cochlear Center for Hearing and Public Health, which is supported in part by a philanthropic gift from Cochlear, Ltd. The funders listed above have no role in both the conduct and outcomes of the study.

Contributors

All authors contributed to the conceptualization of this manuscript (JJS, EP, AH, KP, OS, JW, JRZ, ASD). JJS and EP drafted the manuscript as co-first authors and all other authors contributed substantial feedback and writing for revisions, including a member of the CHW team at SKCCC (OS). ASD and JRZ advised the manuscript's development as co-senior authors and principal investigators of the grant awarded by the Merck Foundation.

Acknowledgements

The authors would like to acknowledge the support of the Merck Foundation in this program of research. The authors would also like to acknowledge Dr. Debra Roter and Ms. Marielle (Mari) Bugayong for their guidance and expertise.

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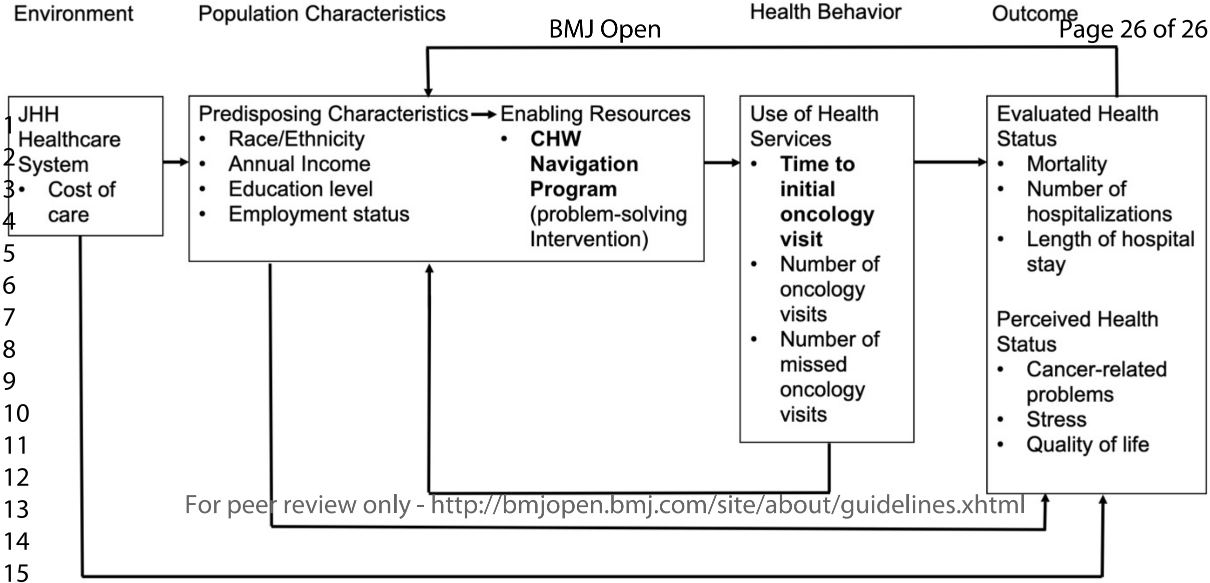
FIGURE LEGEND

Figure 1. Adapted Andersen’s behavioral model for health care utilization

The CHW navigation program serves as an *enabling resource* for promoting appointment-keeping and follow-up (i.e., retention). In the model, the time to initial oncology treatment is defined as the time between the patient’s first cancer diagnosis and the start of cancer treatment. Furthermore, health care utilization encompasses the provider’s *recommended* use of health care services, and the number of oncology visits, number of missed oncology visits, mortality, number of hospitalizations, and length of hospital stay are used as a proxy to measure this concept.


Environment
Population Characteristics
Health Behavior
Outcome
JHH Healthcare System
• Cost of care
Predisposing Characteristics
• Race/Ethnicity
• Annual Income
• Education level
• Employment status
Enabling Resources
• **CHW Navigation Program** (problem-solving Intervention)
Use of Health Services
• **Time to initial oncology visit**
• Number of oncology visits
• Number of missed oncology visits
Evaluated Health Status
• Mortality
• Number of hospitalizations
• Length of hospital stay
Perceived Health Status
• Cancer-related problems
• Stress
• Quality of life