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State-of-the-Science of Patient Navigation as a Strategy for Enhancing Minority Clinical Trial Accrual

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Abstract

Background—Patient navigation programs are emerging, that aim to address disparities in clinical trial participation among medically underserved populations, including racial/ethnic minorities. However, there is a lack of consensus on the role of patient navigators within the clinical trial process, as well as outcome measures to evaluate program effectiveness.

Methods—A review of the literature was conducted of PubMed, Medline, CINAHL, and other sources to identify qualitative and quantitative studies on patient navigation in clinical trials. The search yielded 212 studies, of which only 12 were eligible for this review.

Results—The eligible studies reported on development of programs for patient navigation in cancer clinical trials, including training and implementation among African American, American Indian and Native Hawaiians. Low clinical trial refusal, 4% to 6%, was reported among patients enrolled in patient navigation program. However, few studies reported on the efficacy of patient navigation on increasing clinical treatment trial enrollment.

Conclusion—Outcome measures are proposed to assist in developing and evaluating the efficacy and/or effectiveness of patient navigation programs that aim to increase participation in cancer clinical trials. Future research is needed to evaluate the efficacy of patient navigators in addressing barriers to clinical trial participation and increasing enrollment among medically underserved cancer patients.

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Keywords

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Introduction

Participation of ethnic minorities and medically underserved populations in clinical trials is critical to achieving progress in cancer control.¹ Successful and timely completion of cancer clinical trials continues to be a challenge and is a limitation to advancing science as too many clinical trials continue to fail due to low patient accrual.² However, clinical trial participation is a daunting process that calls for significant trust, altruism and commitment on the part of the patient. Multiple factors contribute to low clinical trial enrollment in general, and to the disproportionately low enrollment rate among minority patients.³⁻⁵ The proportion of adults expressing a willingness to participate in a trial is well above the proportion recruited into clinical trials.⁶ Patients and their families are often unaware of clinical trials; they may bear misconceptions around the process of randomization, as well as concerns about being “treated like a guinea pig”.⁶⁻⁸ American Indian, Asian American, and African American communities have identified mistrust of medical research and researchers as a reason for their resistance to medical research.^{3,9-11} Immigrant, rural, poor and working cancer patients have cited logistical concerns, including issues with transportation, life responsibilities, lack of insurance and out of pocket expenses, as inhibiting their ability to participate in research.^{3,12,13} Patient navigation programs are currently being explored as a promising approach to address barriers to cancer trial participation among minority and medically underserved populations.

Patient navigation, a process of providing enhanced education and facilitative services to the patient, was first described by Dr. Harold Freeman in Harlem, to improve adherence to breast cancer care among African-American women.¹⁴ Simply stated, patient navigation is a strategy for increasing patients' access to cancer care by helping them overcome barriers in their communities, and within the health care system.^{15,16} Patient navigation comes under various labels, including lay or community health workers, promotoras, etc.; however, regardless of the label, navigators provide a bridge between the patient and the health care system.

The National Cancer Institute's Patient Navigation Research Program (PNRP) represented the most systematic approach to exploring the effectiveness of patient navigation in the delivery of cancer-related care.¹⁷ The effectiveness of patient navigation in overcoming barriers to cancer screening uptake has been documented in the completion of mammogram for breast cancer, Pap test for cervical cancer and colonoscopy for colon cancer.¹⁸⁻²⁰ However, there is scant information on the potential role of patient navigation as a strategy to reduce disparities in cancer clinical trial participation. Patient navigation has been proposed as one approach to increase minority accrual to cancer clinical trials²¹, and studies have suggested that patient navigators can address barriers to clinical trial participation for patients from ethnic minority groups.²² However, there has not been a review of the current

evidence on the efficacy and/or effectiveness of patient navigation as a strategy to increase minority accrual to cancer clinical trials.

We conducted a review of the literature, in order to determine how patient navigators have been used in clinical research to increase minority patient participation in cancer clinical trials and what types of barriers they have addressed, and to elucidate working models of patient navigation in the clinical trial process. Our goal is to synthesize the key features of patient navigation in clinical trial enrollment specific to therapeutic clinical trials, and to propose outcome measures for the evaluation of patient navigation programs that aim to increase accrual to cancer clinical trials.

Methods

The goal of the literature review was to identify and compare both qualitative and quantitative studies on patient navigation (PN) in cancer clinical trials. Only articles indexed in databases of peer-reviewed literature were eligible for this review. A search was conducted for articles indexed in PubMed, Medline and CINAHL, and published in English between January 1, 2005 and December 31, 2012. Studies lacking original research data were excluded.

Although there is an extensive literature available on PN, we focused this literature review on studies that evaluated the use of PN to address barriers to cancer clinical trial enrollment for minority patients. In early 2013, PN was introduced as a formal Medical Subject Heading (MeSH) term. With the guidance of an experienced research librarian, we identified relevant published literature using a combination of terms “patient” AND “navigate” and modified further using formal MeSH headings of “clinical trial”, “community health worker” OR “neoplasm”. The search identified 555 references. A review of the title excluded 343 papers, leaving 212 abstracts for review. A primary reviewer conducted a complete abstract review based on exclusion and inclusion criteria and a secondary reviewer checked the primary reviewer for accuracy and completeness. Six additional articles were identified by review of the reference list of identified articles. Articles evaluating the role of patient navigator to address barrier to minority cancer clinical trial accrual were included. Articles evaluating the role of patient navigator to address barriers to cancer screening, diagnosis, follow-up, treatment, survivorship or end of life were excluded. After applying the inclusion and exclusion criteria, there were 12 data-based articles reporting on PN in cancer clinical trials. Two reviewers independently read each article in full text, evaluated the relevance of retrieved articles, and recorded the main findings of each study in a table. The reviewers abstracted data on study design, participant characteristics, study setting, cancer type, outcome measures including clinical trial enrollment and refusal. Because the available studies were preliminary in nature and because of the heterogeneity of the study design, it was not possible to quantify the specific intervention impact on aspects of minority enrollment using meta-analysis methods.

Results

Study Characteristics

The study characteristics are presented in Table 1. Most of the articles were published in 2010 or later. Five of the articles were descriptive studies reporting on patient navigation (PN) curriculum development and training to address barriers to cancer clinical trial recruitment. Studies reported on clinical trial PN targeting Asian and Pacific Islanders, African American, Latinos/Hispanics and American Indians. Six studies reported outcome on clinical trial enrollment among their study patient population, although three of the six were based on data from the American Indian Walking Forward program in Rapid City, South Dakota. The primary function of the patient navigator as identified in these studies was to increase clinical trial awareness; although other roles included assisting with logistic and cultural barriers.

Access to Clinical Trial Patient Navigator

For many patients, enrolment into a clinical trial often occurs at an institution distant from the healthcare facility where the patient received a cancer diagnosis. Understanding the need to bridge this gap, the programs identified within this review have established the PN as a key bridge between the community and the cancer center. Some programs emphasized the role of the patient navigator to increase clinical participation through increasing awareness, knowledge and access to appropriately matched clinical trials.^{23,24} A presence in the community was deemed to be critical to the success of the University of Southern California program as the nurse patient navigator traveled to the community clinics to enroll patients into the navigation program and accompanied them through the clinical trial process at the referral cancer center.²⁵ Walking Forward program separated the navigation activities into 1) community-to-cancer center navigation, conducted by the community research representative who physically resides either within one of the reservations or in the urban American Indian community; and 2) the patient navigation activities in the context of the cancer center, coordinated by an internal patient navigator.⁹ A variety of other programs positioned a culturally and linguistically competent patient navigator within the cancer center as a member of the clinical trials group (medical oncologist, radiation oncologist, clinical trials nurse and other support staff).^{9,26-29} This was assessed to enhance communication with the cancer team and facilitate advocacy on behalf of the patient.

Training of Clinical Trial Patient Navigator

Among programs reported in this review, elements of the patient navigator training include some combination of education and training on topics including cancer care, communication and active listening skills, motivational interviewing, language barriers, cultural competency, access to community resources, ethics and privacy practices, recordkeeping, and the boundaries of the navigator role.^{9,23,26,28,30} Additional aspects of training required for navigators working with cancer clinical trials include principles of cancer clinical trial design, human subjects research policies, and the risks and benefits of trial participation.²⁸ The initial navigator training often combined didactic and interactive learning, frequently divided over multiple sessions.^{26,28,30} Many of the necessary navigator skills were reinforced through interactive learning including the use of vignettes or role-playing.²⁸ The

interactive learning provided the navigators an opportunity to practice newly learned skills with the benefit of feedback from an instructor and other learners. Following the initial training, some programs evaluated the training using pre- and post-training questionnaires to assess clinical trial and navigation knowledge or more formalized skill evaluation using standardized patient actors and *a priori* checklists for simulated patient interactions.^{23, 26, 30} Some programs reported on periodically scheduled continuing education for patient navigator to allow navigators to continue to build on their skills and to offer one another support.^{26, 28}

Barriers Addressed by Patient Navigators

Building on the knowledge gained through formative research, patient navigators addressed barriers to clinical trial access. Depending on the program, the invitation to partner with a patient navigator was extended to a specific minority group, all ethnic minority patients, or to patients with a specific diagnosis (i.e., disease site). Although some patients declined participation, 11% within the Walking Forward program³¹, a majority accepted the PN program. Barriers to cancer care and clinical trial participation were often concurrently identified during the clinical trial screening process, although some programs initiated a more coordinated screening process starting with the review of pathology to determine potential clinical trial eligibility.²⁹ A majority of programs generally identified the various barriers addressed by instituting the PN clinical trial program, but few provided details based on individual patient interaction. In the analysis of barriers identified by patient navigator within the Walking Forward program³¹, 54% identified a need for financial assistance and 35% for psychosocial support with an increasing number of patients requiring both these services over the course of their cancer care.

Clinical Trial Enrollment Outcome

Table 2 presents published literature on PN clinical trial programs reporting clinical trial enrollment as a primary outcome. Comparison between PN programs is limited as the availability, eligibility and infrastructure support for clinical research varied between programs. Cancer patients were offered participation in PN services at the initial consultation^{25,27,31} or upon the referral of the cancer care team during the initial assessment for clinical trial eligibility.²⁹ Most reported enrollment data among patients deemed eligible for an open clinical trial, although this overlooks the large need identified by most programs which is the lack of appropriately matched available clinical trials for their target population. Factors related to protocol availability, disease site or stage of presentation and restrictive eligibility criteria excluded 50% to 73% of minority patients from clinical trial participation.^{13,22,25,27,29} More specifically among American Indian patients within the Walking Forward program, 27% were excluded due to advanced stage, co-morbidities or performance status.¹³ Studies reported clinical trial enrollment that ranged 61% to 86% among study eligible minority patients, demonstrating patients' willingness to participate in clinical trials.^{25,27,29} Furthermore the documented increase in American Indian patients representation within the cancer center overall clinical trial accrual, from the 1% reported in published studies to the 10% achieved within the Walking Forward program speaks to the potential for progress that can be achieved with a clinical trial PN program.^{5,13,32} However,

the program was not designed to evaluate the separate contribution of the PN program to this increase.

Discussion

In this review of patient navigation within clinical trials, we identified 12 studies describing curriculum development, training, implementation and program evaluation. Despite the limitations of the small number of reports within this field, early successes in increasing minority clinical trial enrollment are documented.^{13,25,27,29} The various programs share a common goal to increase awareness and access, and to reduce barriers to participation in clinical trials. The heterogeneity of the eligible studies, with respect to study design, target populations, context of navigation (in center, in community, or both), as well as reported clinical trial enrollment outcomes, limited the ability for comparison across studies. Nonetheless, the potential value of these early documented reports cannot be overlooked, as the reported clinical trial refusal rates among study-eligible minority patients engaged in patient navigation program are low.^{13,25,29}

The programs identified by this review point to essential characteristics patient navigation (PN) programs on facilitate participation in clinical trials: community engagement, cultural competency and integration within the cancer care team. The eligible studies indicate that such programs must be designed to address the individual patient-level and community-level barriers and facilitators of clinical trial participation. A process of community engagement either through community dialogue, community surveys, cancer survivors' focus groups and conversations with multiple stakeholders informed the design of the Ho'okele I ke Ola Native Hawaiian (Navigating to Health) program, Walking Forward American Indian South Dakota program and University of Southern California African American Breast Cancer program.^{22,25,30} Dialogue with community outreach workers within the Native Hawaiian communities identified the centralization of cancer care in Honolulu as a logistical barrier for potential patient navigators and cancer patients residing in neighboring islands.³⁰ Leading up to the development of the PN clinical trial program in Rapid City, South Dakota, a survey of cancer patients documented higher levels of medical mistrust and lower satisfaction among Native American compared to non-Native American cancer patients.³³ These findings supported the multifaceted development of the Walking Forward program with increased time and funds allocated to engaging multiple Native American communities.²²

Lessons to be learned from review of these studies include the need to establish community support and trust within and outside of the cancer center for clinical trial navigator program. Rapid City Regional Hospital developed the Walking Forward program based on a strong community based participatory process, which ultimately lead to a clinical trial patient navigation program that responded to the community needs and resulted in increased American Indian cancer patients enrollment in cancer treatment clinical trials.^{22,34} Challenges identified by studies reported in this review are the low number of available clinical trials for minority patients, who may be deemed ineligible due to presentation at higher cancer stages and increased co-morbidities.^{13,24,29} Exclusion of potentially clinical trial eligible patients due to co-morbidities has been documented among African American

cancer patients and is a persistent challenge for minority patients accrual into clinical trials.³⁵

The available evidence presents a number of strengths, with regard the design of PN, areas to be covered in navigator training, as well as potential outcome measures for clinical trial PN. However, some limitations are also apparent, including retrospective program descriptions, and a lack of between-group comparisons, even in the context of cohort designs. The eligible studies also present a myriad of additional limitations that are summarized in Table 2. The heterogeneity of outcome measures specific to PN clinical trial outcomes limits comparison across studies and thus a need exists to use more robust tools to measure outcomes, including linkage with cancer registries to assess long term impact on survival. The low number of eligible publications identified by this review, despite an increasing number of reports of community oncology programs utilizing PN services, suggests the possibility of reporting bias. This is especially relevant, as four of the 12 eligible studies were based on the Walking Forward Program. Additional and larger studies are needed across minority populations, to assess the efficacy and ultimately, the effectiveness of PN as a strategy to increase clinical trial participation.

Reflecting on the larger body of research available within the area of PN in cancer screening and diagnosis, metrics for evaluating patient centered and cancer care outcomes have been proposed.^{36,37} Studies reporting from the National Cancer Institute sponsored Patient Navigation Research Program (PNRP) support a more rigorous approach to conducting PN effectiveness research.^{17,38} Primary outcome of interest include time to diagnostic resolution, time to initiation of treatment and satisfaction with care.^{17,38} Clearly, early in the development of PN in clinical trial, a similar approach in evaluating and reporting of clinical trial PN program outcomes is needed. In Table 3, we propose similar key outcome measures to assess clinical trial PN efficacy/effectiveness; completion of clinical trial eligibility screening, clinical trial enrollment, and clinical trial study completion. In addition we propose more proximal measures of clinical trial PN outcomes that can inform program evaluation including race/ethnicity data, cancer type and stage at time of PN encounter, barriers to clinical trial enrollment identified (patient or study design) and clinical trial refusal. This ultimately would allow for comparison of PN outcomes across programs designed to increase minority enrollment in clinical trials.

Although not reported in the publications reviewed, development of an easily accessible, HIPPA secure and reliable data collection system is fundamental to reporting data outcomes. Many of the data points necessary to outcome measures can be best acquired from the medical record system, although pertinent issues around barriers identified and addressed must be collected to document the unique value of the patient navigator within the cancer clinical trial team. The Walking Forward Program reported increased patient satisfaction with the use of PN services.³⁴ Outcome measures that reflect patient centered experience with PN services include measures of satisfaction with the interpersonal relationship with the navigator and overall cancer care. National Cancer Institute Patient Navigation Research Program (PNRP) has validated two such measures, Patient Satisfaction with Cancer-Related Care (PSCC) scale³⁹ (Jean-Pierre et al., 2011) and Patient Satisfaction

with Interpersonal Relationship with Navigator (PSN-I)⁴⁰, both of which can be incorporated into the assessment of clinical trial PN program.

Sustainability of a clinical trial PN program is dependent on documenting impact on increasing clinical trial enrollment and cost associated in supporting such a program. Few studies have begun to address cost effectiveness issues around PN services and challenges to these measures include the heterogeneity of PN programs.^{41,42} Measuring cost-effectiveness of clinical trial patient navigation may be further complicated by the more complex financial arrangements existing in industry and non-industry sponsored clinical cancer research.⁴³ In addressing the limitation in resources to support PN for recruitment/retention of minority patients in clinical trials, benefits beyond those normally accounted in cost-effectiveness analysis must be taken into consideration; for the consideration of broader societal benefits is at the core of clinical research.

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Table 1
Summary of Published Cancer Clinical Trial Patient Navigation Studies: 2005-2012

STUDY	CANCER	DESIGN	FOCUS OF STUDY	STUDY SITE/ PARTICIPANTS	NAVIGATION OUTCOME MEASURES	PATIENT NAVIGATION FUNCTION	STUDY LIMITATIONS
CURRICULUM DEVELOPMENT AND PN TRAINING							
Braun KL, et al, 2008 ³⁰	N/A	Descriptive study	Patient navigator curriculum and training; Asian and Pacific Islanders	Native Hawaiian Cancer Network (Imi Hale) 62 patient navigators trained	N/A	N/A	<ul style="list-style-type: none">Limited evaluation of navigator's knowledge and skills gainedNo data on the effectiveness of the training curriculum
Bryant DC, et al, 2011 ²⁶	Lung, Esophageal	Descriptive study	Patient navigator curriculum and training; African American	University and community cancer centers (3 sites, Georgia) 15 cancer team members participated in training	N/A	N/A	<ul style="list-style-type: none">Small sample size of navigators trainedNo data on the effectiveness of the training curriculum
Schapira L, et al, 2011 ²³	N/A	Descriptive study	Community health workers training on clinical trials; African American	Community and University medical center (Boston, Massachusetts) 41 community health workers	N/A	N/A	<ul style="list-style-type: none">No data on the effectiveness of the training curriculum
Steinberg ML, et al, 2006 ²⁸	N/A	Descriptive study	Patient navigator curriculum development and training; African American	Community medical center (Los Angeles, California) 31 navigators trained, 22 active as navigators	N/A	Patient navigators identify barriers to care at the time of clinical trial recruitment during the initial consultation, culturally and linguistically matched to patient	<ul style="list-style-type: none">Limited data on the effectiveness of the training curriculum
Holmes DT, et al, 2012 ²⁵	Breast	Prospective study	Clinical trial enrollment among African American (AA) patients	University cancer program (Los Angeles, California) 132 AA breast cancer patients	Clinical trial enrollment among patients enrolled in patient navigation program	Patient navigators addressed clinical trial awareness, access and coordination of care	<ul style="list-style-type: none">Limited to one genderNo systematic documentation of barriers identified or addressed by navigators
Moffitt K, et al, 2010 ²⁴	Multiple	Program analysis	Statewide clinical trials navigation service that can be accessed via the web or phone (bilingual Hispanic navigation service)	Statewide clinical trial matching program (Florida) 6350 patient profiles. Florida: higher Hispanic population	Patient awareness; trial enrollment	Patient navigators provide clinical trial information by phone, addressed clinical trial awareness and language barrier	<ul style="list-style-type: none">No clinical trial enrollment dataNo race/ethnicity data
Proctor JW, et al, 2011 ²⁷	Lung, Head and Neck, Breast, Brain	Prospective study	Clinical trial enrollment among radiation patients; racial/ethnic minority	Community cancer program (New Castle, Pennsylvania) 144 radiation eligible cancer patients	Clinical trial screening and accrual data (radiation eligible cancer patients only)	Underinsured or racial/ethnic minority patients offered patient navigation services at initial consult	<ul style="list-style-type: none">No systematic documentation of barriers identified or addressed by navigatorsNo race/ethnicity data
Wujcik D, et al, 2010 ²⁹	Multiple	Prospective study	Clinical trial enrollment within a minority based community oncology	Community clinical oncology program (Nashville, TN) 55% of patients treated at hospital AA, 1,125 patients screened	N/A	Barriers identified include: transportation, lack of insurance, poor communication, missed appointments	<ul style="list-style-type: none">No systematic documentation of barriers identified or addressed by navigators

STUDY	CANCER	DESIGN	FOCUS OF STUDY	STUDY SITE/ PARTICIPANTS	NAVIGATION OUTCOME MEASURES	PATIENT NAVIGATION FUNCTION	STUDY LIMITATIONS
			program; African American (AA) program; African American (AA)				
WALKING FORWARD PROGRAM							
Petereit DG, et al., 2008 ⁹	Multiple	Descriptive study	Patient navigator program; American Indians (AI)	Community cancer center (Rapid City, South Dakota) 231 AI patients	N/A	213 patients navigated, median contact 15 for those on treatment and 4 for those in follow-up	<ul style="list-style-type: none">Limited documentation of barriers identified or addressed by navigators
Guadagnolo BA, et al. 2009	Multiple	Prospective study	Clinical trial enrollment with patient navigation program; American Indians (AI)	Community cancer center (Rapid City, South Dakota) 891 patients, 94 AI	Enrollment in a cancer treatment trial	All AI patients enrolled in clinical trial studies participated in the patient navigation service	<ul style="list-style-type: none">Data on clinical trial eligibility rate not available
Guadagnolo BA, et al. 2011 ³¹	Multiple	Prospective study	Patient navigation impact on clinical trial enrollment; American Indians (AI)	Community cancer center (Rapid City, South Dakota) 332 AI	Clinical trial accrual (treatment adherence was primary outcome)	332 AI participated in patient navigation program, 72 (22%) enrolled on therapeutic or cancer control trial	<ul style="list-style-type: none">No control group
Petereit DG, et al., 2011 ²²	Multiple	Retrospective analysis	Clinical trial patient navigator program; American Indians (AI)	Community cancer center (Rapid City, South Dakota)	Trial enrollment	332 AI cancer patients participated in patient navigator services, median number of contacts 12	<ul style="list-style-type: none">No control group

Table 2

Clinical Treatment Trials Outcome Summary

STUDY	TIME	CANCER	RACE/ETHNICITY	MINORITIES ON CLINICAL TRIAL			OVERALL ENROLLMENT	CANCER CENTER PARTICIPATION
				ENROLLMENT	REFUSAL			
Guadagnolo BA, et al., 2009 ¹³	2006-2008	Multiple	American Indian	2006-2008 94 American Indian screened, 6 (6%) enrolled in a clinical treatment trial	4%		891 screened 78 (9%) enrolled 45 (5%) refused (Data on clinical trial eligibility rate not reported)	891 screened, 89% Caucasian, 11% American Indian, <1% Hispanic, < 1% Asian
Wujcik D, et al., 2010 ²⁹	2001-2007	Multiple	AfricanAmerican	2005-2007 data 556 screened 179 eligible 138 (79%) enrolled 84 (61%) African American	4%		2001-2007, 1,125 patients screened 343 eligible 233 (68%) enrolled	Nashville General Hospital at Meharry, 2005-2007 total 138 patients enrolled: 61% African American, 36% White, 2% Hispanic, 1% Asian Pacific Islanders
Proctor JW, et al., 2011 ²⁷	2006-2007	Multiple, radiation only trials	Diverse group	46 screened 7 eligible 5 (71%) enrolled	N/A		144 screened, 24 eligible 15 (62%) enrolled	Minorities enrolled into studies at same rate as the general cancer center population
Holmes DR, et al., 2012 ²⁵	2007-2008	Breast	African American	132 screened 59 eligible 51 (86%) enrolled	6%		34 other enrolled (22 Hispanic, 8 whites, 4 Asians)	2007-2008 USC Norris, African American accrual to cancer clinical trial increased from 3% to 7%

Table 3
Summary of Recommended Patient Navigation Clinical Trial Outcome Measures

DOMAIN	COMMON DATA ELEMENTS	KEY OUTCOME MEASURES*
Clinical Trial Recruitment	<ul style="list-style-type: none"> Referral date and source Type and stage of cancer Race/Ethnicity Communication strategy about the trial Survey of PN identified barriers Clinical trial eligibility screening Phase of Trial 	<ul style="list-style-type: none"> Target population's knowledge about clinical trials Proportion completing eligibility screening Proportion willing to consider trial participation
Clinical Trial Enrollment	<ul style="list-style-type: none"> Survey of barriers addressed with each contact Frequency and length of each contact Date cancer treatment initiated Date of clinical trial enrollment If disenrolled from trial, reasons for termination 	<ul style="list-style-type: none"> Proportion enrolled in a trial Proportion randomized in a trial
Clinical Trial Completion	<ul style="list-style-type: none"> Patient satisfaction with PN services Patient satisfaction with cancer care Dates for follow-up 	<ul style="list-style-type: none"> Proportion completing the clinical trial

* By race/ethnicity and/or navigation status