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PATIENT NAVIGATION:

STATE OF THE ART, OR IS IT SCIENCE?

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Abstract

Background—First implemented in 1990, patient navigation interventions are emerging as an approach to reduce cancer disparities. However, there is lack of consensus about how patient navigation is defined, what patient navigators do, and what their qualifications should be. Little is known about the efficacy and cost effectiveness of patient navigation.

Methods—We conducted a qualitative synthesis of published literature on cancer patient navigation. Using the keywords "navigator" or "navigation" and "cancer," we identified 45 articles from Pubmed and reference searches that were published or in press through October 2007. 16 provided data on efficacy of navigation in improving timeliness and receipt of cancer

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Condensed abstract: A qualitative synthesis was conducted to evaluate cancer patient navigation, with patient navigation services defined and differentiated from other outreach services. Overall there is evidence for some degree of efficacy for patient navigation in increasing participation in cancer screening and adherence to diagnostic follow-up care following an abnormality.

screening, diagnostic follow-up care, and treatment. Patient navigation services are defined and differentiated from other outreach services.

Results—Overall there is evidence for some degree of efficacy for patient navigation in increasing participation in cancer screening and adherence to diagnostic follow-up care following an abnormality, with increases in screening ranging from 10.8% to 17.1% and increases in adherence to diagnostic follow-up care ranging from 21% to 29.2%, when compared to control patients. There is less evidence regarding efficacy of patient navigation in reducing either late stage cancer diagnosis or delays in initiation of cancer treatment or improving outcomes during cancer survivorship. There were methodological limitations in most studies, such as lack of control groups, small sample sizes, and contamination with other interventions.

Conclusions—Although cancer-related patient navigation interventions are being increasingly adopted across the U.S. and Canada, further research is necessary to evaluate their efficacy and cost-effectiveness in improving cancer care.

Keywords

neoplasms; healthcare disparities; quality of health care; delivery of health care

I. INTRODUCTION

Continued advances in cancer screening and treatment are evident in the overall reduction in morbidity and mortality among those diagnosed with cancer.1 Uninsured, African American, Hispanic, and low-income patients are less likely than white, high-income, and insured patients to receive recommended cancer care.2⁻³ Those most at risk for advanced stage at cancer diagnosis and high mortality include racial/ethnic minorities and socio-economically disadvantaged populations who are more likely to be uninsured.2 These same populations experience significant delays in completing follow up care once a screening abnormality has been detected.4⁻⁵ While the reasons for these disparities are complex and not completely understood, research has identified numerous patient, provider, and health system barriers for these at-risk populations.6⁻⁷ A growing body of literature indicates that known barriers to care interfere with timely access to diagnosis and treatment once a screening abnormality has been identified.8⁻¹⁸

In an effort to reduce these disparities, patient navigation has been proposed an as innovative intervention to addresses known barriers to obtaining cancer care. Patient navigation is a model of care that is rapidly expanding in underserved communities and medical institutions across the nation.19⁻²⁰ However, despite proliferation of patient navigator programs, there is little consensus about what constitutes patient navigation services and little information on the efficacy of patient navigation in improving outcomes. The goals of this paper are to: (1) describe the evolution of patient navigation as a model to address cancer disparities; (2) review current literature that defines patient navigation and its impact in cancer care; and (3) describe the goals of the Patient Navigation Research Program (PNRP), sponsored by the National Cancer Institute (NCI) and the American Cancer Society (ACS) as a means to address existing gaps in our knowledge regarding the efficacy of patient navigation. In synthesizing the literature, we sought to investigate the following questions: (1) What is patient navigation? (2) What do patient navigators do? (3) How is patient navigation distinct from existing cancer care services? (4) What are the qualifications of a patient navigator? (5) What are the target populations served by patient navigation programs? (6) What are the intended outcomes of patient navigation? (7) Where in the cancer care continuum do patient navigators provide services? and (8) What is the efficacy of patient navigation?

Historical Evolution of Patient Navigation in Cancer Care

The prevention, diagnosis, and treatment of cancer are complex processes that often require consultation with multiple medical specialists in multiple settings, utilizing numerous medical tests.21 To understand the unique challenges faced by disadvantaged populations in accessing these complex processes, the ACS conducted a series of hearings in 1989 with low-income Americans throughout the United States. The results of these hearings were published in a report by the ACS entitled *Report to the Nation: Cancer in the Poor*.6 It found that poor people face significant "obstacles" to accessing cancer care services which prevent them from obtaining needed care, including: (1) widespread financial barriers, such as being unable to afford health insurance; Medicaid or Medicare ineligibility; losing employment that provides health insurance; and lack of affordable cancer services; (2) logistical barriers, such as a lack of transportation, living at a far geographic distance from health care, lack of reminder systems, and lack of understandable cancer information; and (3) sociocultural barriers, such as limited social support and inadequate health literacy.

In response to the results of the ACS report, Dr. Harold P. Freeman partnered with the ACS to create the first patient navigation program in Harlem, New York in 1990 targeting women with historically poor breast cancer outcomes.21⁻²³ This innovative program assisted low-income women in overcoming barriers to breast cancer screening and follow-up care. In addition to expanding screening and education services throughout the community, specified members of the community provided patient navigation services to women with a clinical finding suspicious for cancer.23

Since the pioneering work of Dr. Freeman, there has been a growing commitment to support patient navigation services. In 2001, the President's Cancer Panel recommended that funding be provided to support community-based programs, such as patient navigator programs, to assist people in obtaining "cancer information, screening, treatment, and supportive services."24 As a result, there has been an expansion in programs nationwide, with funding from private foundations, including the ACS, the Avon Foundation, and the Susan B. Komen Breast Cancer Foundation,19 as well as local government, state government, federal government, and community organizations. In 2003, there were over 200 cancer care programs nationwide providing patient navigation as identified by the NCI. 19 By 2007, the ACS funded more than 60 patient navigation programs across the United States.25

The federal government has made a substantial commitment to patient navigation through support of three separate programs. In 2005, NCI's Center to Reduce Cancer Health Disparities (CRCHD) funded eight sites for the PNRP (and in collaboration with the ACS, a ninth site joined the PNRP). This program will test community-based navigation programs using a control group. In June 2005, the Patient Navigator, Outreach, and Chronic Disease Prevention Act of 2005 authorized federal grants to hire and train patient navigators to assist patients with cancer and other serious chronic diseases to obtain access to timely diagnostic, treatment, and follow-up care,21 and \$2.9 million was appropriated in 2007 for this initiative. In 2006, the Center for Medicare Services (CMS) funded six demonstration sites for pilot programs targeting minority Medicare beneficiaries with the goal of overcoming barriers in screening, diagnosis, and treatment of cancer.26 Despite the interest in patient navigation and funding of these programs, there is limited published information regarding their efficacy and cost-effectiveness.

II. METHODS

Study Identification

The goal of the literature review was to identify and summarize both descriptive and efficacy literature on patient navigation. A review of research literature in the National Library of Medicine was conducted in October 2007 by searching the PubMed database to identify articles describing patient navigation programs that were published at any time in English with human participants. Reference lists of identified articles were also reviewed for relevant publications. The inclusion criteria specified: (1) published original articles; and (2) a description of a patient navigator program related to cancer treatment, diagnosis, or screening. The PubMed database was searched using the keywords "navigator" or "navigation" and "cancer." The search produced 893 citations, however, when abstracts of each article were reviewed only 35 were related to cancer patient navigation.23,27⁻60 An additional seven studies were found in reference lists of articles identified in the search or were included in the same journal issue as another published paper.19,21-22,61-64 Three additional articles were identified by study authors.65-67 All forty-five articles were reviewed, and any article that described a patient navigator program was retained for further analysis. Twenty-eight articles provided descriptive information on cancer patient navigator programs in sites across the United States and Canada. Of these articles, sixteen provided information on outcomes of a patient navigation intervention (Table 1). These articles were used to provide descriptive information on patient navigation and evidence regarding its efficacy.

III. RESULTS

WHAT IS PATIENT NAVIGATION?

Several definitions of patient navigation have been published.21⁻22[,]68⁻69 While variations do exist, patient navigation is generally described as a barrier-focused intervention that has the following common characteristics:

- Patient navigation is provided to individual patients for a defined episode of cancer-related care (e.g., evaluating an abnormal screening test).
- While tracking patients over time is emphasized, patient navigation has a definite endpoint where services provided are complete (e.g., patient achieves diagnostic resolution following a screening abnormality).
- Patient navigation targets a defined set of health services that are required to complete an episode of cancer-related care.
- Patient navigation services focus on the identification of individual patient-level barriers to accessing cancer care.
- Patient navigation aims to reduce delays in accessing the continuum of cancer care services, with an emphasis on timeliness of diagnosis and treatment and a reduction in number of patients lost to follow up.

WHAT DO PATIENT NAVIGATORS DO?

Despite its narrow barrier-focused definition, patient navigation has been operationalized quite broadly in practice. The term "navigator" has been applied to any type of service that assists people in overcoming obstacles from screening to treatment, as well as coping with challenges during survivorship. In our analysis of published articles that describe patient navigation services, we identified four areas where patient navigators frequently intervene: (1) overcoming health system barriers; (2) providing health education about cancer across

the cancer continuum from prevention to treatment; (3) addressing patient barriers to cancer care; and (4) providing psychosocial support. To overcome health system barriers, patient navigators may coordinate cancer diagnostic or treatment care from multiple providers, assist patients with completing medical paperwork, schedule, confirm, reschedule, and attend appointments, and facilitate patient-provider communication. 27⁻28³1³4³6⁻37⁴0⁴45³8⁻53⁵5⁻56⁵58⁻59⁶1¹70 When providing health education, patient navigators provide written information, discuss diagnostic and genetic tests, discuss treatment options, and answer patients' questions.28³1³4³6⁴5⁵0⁻53⁵55⁵56⁵58⁻59⁶1 To overcome patient barriers to cancer care, a patient navigator may address issues such as lack of transportation, financial and insurance barriers, lack of child care or language translation, low health literacy, or low literacy.28⁴0⁻41⁵0⁵3⁵56⁷70 Patient navigators also provide psychosocial or emotional support, either directly or by referring patients to social workers or cancer support groups.28⁵0⁻51⁵5⁵56

HOW IS PATIENT NAVIGATION DISTINCT FROM EXISITING CANCER CARE SERVICES?

Patient navigation shares characteristics with other models of patient assistance.30 For instance, hospital-based social workers may provide health education materials to oncology patients, and community health workers, lay health advisors, or promotoras may promote cancer screening in the community. In addition, case management and patient advocate models often provide similar services that patient navigators provide, but these models can also be distinctively different.

Case managers work to assist the client in achieving optimal wellness, self-management, and functional capability by linking clients with service providers and resources throughout the continuum of health and human services and care settings.71 While the principles of case management (case identification, identifying barriers to care, developing individual plans to overcome barriers, tracking over time) are embedded in patient navigation, there are distinct differences. Most importantly, patient navigation focuses on one health condition, instead of the broader goal of case management to improve health in general. In addition, patient navigation tends to track to completion of a discrete set of health services, instead of long-term follow up. Similar to patient navigators, a patient advocate helps resolve issues about health care, medical bills, and job discrimination related to a patient's medical condition.72 However, the focus of patient advocates is on improving the health care system, rather than delivering care to individual patients.26 While patient navigators may also perform similar tasks as patient advocates, they aim to overcome individual and logistical barriers to prevention, diagnosis, and treatment of a health concern.

WHAT ARE THE QUALIFICATIONS OF A PATIENT NAVIGATOR?

Our review of the published literature found great variation in the personnel providing patient navigation services. Patient navigation services were frequently provided by a lay patient navigator,28⁻29[,]50[,]56 while several programs described navigators with undergraduate degrees,32⁻33[,]65[,]67 master's degrees,32⁻33 nurse practitioners or nurses, 55[,]58⁻59 social workers,57⁻58 health educators,59 clinic staff members,49 research assistants,45[,]52 and cancer survivors.41[,]59 Typically, patient navigators are paid personnel, rather than volunteers.

While it appears that most patient navigators in the United States are receiving some training, it is unclear what the quality or content of the training is. In one evaluation of patient navigation in Canada, virtually none of the patient navigators had received navigation training, however, the patient navigators evaluated were either nurses or social workers and therefore had extensive knowledge of medicine or case management.73

WHAT ARE THE TARGET POPULATIONS SERVED BY PATIENT NAVIGATION PROGRAMS?

Patient navigator programs reviewed serve mainly those populations most at risk for poor cancer outcomes. The programs in our review targeted many diverse and underserved populations in the United States, including inner-city residents,

23[,]27[,]32⁻33[,]37[,]40[,]45[,]56[,]63[,]65 Native Americans,28⁻29[,]50[,]53 low income populations,43 minority populations,35[,]49[,]57⁻58 and rural residents.67 However, several patient navigation programs did not specifically target underserved populations31[,]36[,]41[,]51⁻52[,]55[,]59. For example, patient navigation has been provided to medical center

patients31,34,36,41,48,51,55,59,65 and patients in a managed care organization.52

WHAT ARE THE INTENDED OUTCOMES OF PATIENT NAVIGATION?

Our review found most patient navigation programs have been designed to improve the outcomes for cancer in one specific site of the body, such as breast cancer. By far, most programs described in the published literature focus on improving outcomes for breast cancer.27⁻29³1⁻32³4⁴0⁻41⁵1⁶3⁶5 Other patient navigation programs target cervical cancer,33³5⁴9 colorectal cancer,45⁴8 prostate cancer,57⁻58 lung cancer,55 and head and neck cancer.36 Only five programs reported navigation programs targeting multiple cancer sites.37⁴3⁵0⁵59⁶7

WHERE IN THE CANCER CARE CONTINUUM DO PATIENT NAVIGATORS PROVIDE SERVICES?

Patient navigation services also target improving cancer outcomes across the cancer care continuum. Several programs were implemented to increase screening, 28⁻29^{,35,45,48⁻49^{,57⁻58} improve follow up care following an abnormal cancer screen, 27⁻28^{,32⁻34,37,40,43,48,51,65} reduce time from diagnosis to treatment of cancer,55 improve cancer treatment and the psychosocial experience of cancer treatment, 34^{,36,40⁻41,56,59,67} and improve accrual and retention in clinical trials.50,56 Less frequently, patient navigators have provided health care,55 assisted in accrual and retention of clinical trial participants,28 recruited individuals for cancer screening,28 and sought to increase compliance with referrals to BRCA 1/2 genetic testing.52 To date, no published study has evaluated the efficacy of a patient navigation intervention for cancer survivors.}

WHAT IS THE EFFICACY OF PATIENT NAVIGATION?

Sixteen studies evaluated the efficacy of a patient navigation intervention, using several different study designs (Table 1), all with different outcomes. Most studies focused on receipt of cancer diagnostic care and treatment services. Though the majority of these sixteen published studies targeted improving outcomes in diagnostic breast health services, 27:29:32:34:41:51:63:65 none of the studies reviewed had comparable outcomes. Most published studies used prospective designs comparing participants who had received patient navigation to patients who did not receive navigation.29:33⁻35:37:41:45:52:57⁻58:65 Seven studies (43.8%) randomly assigned participants or clinics to a patient navigation intervention or comparison group.29:34:45:52:57⁻58:65 Two studies were limited by low sample sizes. 41:52

Improving Screening Rates—Six published articles provide evidence of the efficacy of patient navigation in improving screening rates for three cancers.29·35·45·48·57⁻⁵⁸ The improvement in the rate of adherence to screening ranged from 10.8% to 17.1%, when patient navigation was compared to a control group. Limitations in the research designs preclude definite conclusions regarding efficacy. Some articles reported that patient navigation was combined with educational outreach,57⁻⁵⁸ included in a multifaceted

cognitive-behavioral intervention,35 or combined with improvements in the hospital's gastrointestinal suite,48 making it difficult to determine whether patient navigation alone significantly increased screening rates. In two studies,29·45 participants were randomized to the patient navigation intervention or control arm, whereas another two studies57⁻58 compared patient navigation to other educational interventions.

Improving Adherence to Diagnostic Services Following an Abnormality—

Several published articles reported patient navigation resulted in improvements in both adherence to follow-up visits after a screening abnormality (improvements ranging from 21% to 29.2% when patient navigation was compared to a control group) as well as timeliness of obtaining care from screening abnormality to diagnostic resolution among patients screened for breast, cervical, prostate, and colorectal cancer.27³2⁻³4³7⁴8⁵1⁶⁵ Only two studies randomly assigned to a patient navigation intervention or a usual care group.34[,] 65 Other studies used historical comparisons or study non-participants. 27^{,32⁻³34^{,37}48^{,51,63} In addition, three studies combined patient navigation with counseling,32⁻³⁴ making it difficult to determine whether improvements in follow up care were due to patient navigation or more intense psychosocial intervention.}

Stage of Cancer Diagnosis—The one study that examined the effect of patient navigation on stage of cancer diagnosis found reductions in late stage cancer diagnosis associated with an intervention that included patient navigation, free cancer screening, and culturally sensitive health education.63 Because this study involved a multimodal intervention, it is impossible to draw conclusions regarding the effect of the patient navigator intervention alone on stage of cancer diagnosis.

Improving Cancer Treatment—The information regarding the impact of patient navigation on timeliness of initiation of cancer treatment is mixed. One study found no significant improvement in timeliness of initiation of breast cancer treatment for patients who received patient navigation and counseling when compared to non-participants,32 whereas a second study found that patients who received patient navigation and counseling had faster initiation of breast cancer treatment than participants randomized to usual care.34 The information obtained from both of these studies is limited because the patient navigation intervention was combined with other services.

Implications of Existing Research—Despite the flurry of interest and large financial investment in implementing patient navigation programs nationally, there remains only limited evidence of its efficacy as a means to reduce cancer health disparities. In order to convert these demonstration projects into long-lasting public policy, scientifically rigorous efficacy data are needed to demonstrate the benefits of patient navigation. In order to achieve this goal, there needs to be standardization in the definition of patient navigation, including its tasks, target population, and intended outcomes. Standard metrics to assess the benefit of existing programs are paramount, and high-quality training should be provided to patient navigators. To date, the PNRP is the only large scale research study to examine the effectiveness of patient navigation.

THE PATIENT NAVIGATION RESEARCH PROGRAM (PNRP)

The PNRP, a five-year multi-site clinical trial, is designed to provide data regarding the efficacy and cost effectiveness of the patient navigation intervention model.74 Eight academic research institutions and one health board serving underserved populations were awarded funding in 2005. The PNRP defines patient navigation as support and guidance offered to persons with an abnormal cancer screening test or a cancer diagnosis with the goal of accessing the cancer care system and overcoming barriers to timely, quality care. In the

PNRP, patient navigation targets those who are most at risk for delays in care, including racial and ethnic minorities, patients from low-income populations, uninsured patients, and patients from rural areas who have an abnormal cancer screening test for breast, cervical, colorectal, or prostate cancer. PNRP patient navigators identify individual barriers to care and then work with the health care team and other community agencies to assist patients in overcoming those barriers.

Patient Navigator Training—The PNRP National Patient Navigator Training and Education Committee provides fundamental or core training across all sites.75 The national training is supplemented by local training at each of the sites. This committee has successfully implemented two in-person trainings for over 250 patient navigators from PNRP, the ACS, and CMS patient navigation programs. The trainings were implemented using multiple adult learning modalities, including traditional lecture, interactive formats, and role play with case scenarios. The training curriculum covered topics such as overview of cancer, cancer screening, cancer treatment, communication, culture and diversity, barriers to care, and mapping resources. The efficacy of training was evaluated using a pre- and posttest developed by the training committee. Continuing education occurs through regular Webinar training sessions and annual in-person sessions.

Evaluation of the PNRP Study—The PNRP utilized a committee structure to define common data elements and clinical definitions to measure common outcomes consistently across sites. Ultimate outcomes of navigation are to reduce morbidity and mortality of cancer. PNRP focuses on the measurement of the following intermediate outcomes:

- time from a cancer-related abnormal screening finding to a definitive diagnosis of cancer or resolution of abnormality for those who do not have cancer;
- time from cancer diagnosis to initiation of cancer treatment;
- time from initiation to completion of primary cancer care for patients newly diagnosed with cancer;
- patient satisfaction with cancer care; and
- cost-effectiveness of patient navigation.

In evaluating effectiveness of patient navigation, the goals of PNRP — timely diagnosis and treatment and ease of interacting with the medical care system- would appear to have intrinsic value. The assumption underlying investments in navigation is that these costs will be offset by reductions in mortality following from a more timely resolution of an abnormal cancer screening test than would occur in the absence of navigation. This assumption will be correct if navigation moves a person to an earlier stage of diagnosis (or significantly smaller tumor) than would occur in the absence of navigation. Among individuals who might delay, but will follow-up, stage shift may not be as dramatic, or may not occur at all, depending on length of delay relative to tumor growth. For instance, recent studies report delays of 25 versus 42 days in diagnostic follow-up with and without navigation, respectively.65 This seventeen-day delay, while statistically significant, will not affect stage at diagnosis.

Since navigation in the PNRP is focused on populations that historically are under-screened, navigators will be helping individuals with prevalent tumors that have more advanced stage than are seen in a regularly screened population. In this situation, mortality benefits via stage shift can be expected to be minimal. Navigation could only improve mortality for these prevalent cases (and others with minimal delay) if they improve adherence to effective treatments in populations that would not otherwise comply with therapy. Treatment navigation programs are being developed, 76 and treatment adherence aspects are being

addressed by several of the PNRP sites, but their efficacy for improving survival has not been tested.

IV. DISCUSSION

Despite gains in cancer screening, diagnosis, and treatment, certain populations continue to suffer poor outcomes and higher mortality.3[,] 77 A number of health system and individual barriers exist for underserved populations in accessing and completing recommended cancer care.6[,] 7 Although originally designed to overcome barriers experienced by underserved patients who received a screening abnormality, patient navigation service programs are now widespread throughout the United States and Canada and target a number of different cancer-related outcomes in many populations.

Sixteen published articles provided data on the efficacy of patient navigation. Some published articles indicate patient navigation is associated with improvements in breast, prostate, and colorectal cancer screening, as well as improvements in adherence to follow up visits following an abnormality and reduction in time from abnormal screening to diagnostic resolution for breast, cervical, prostate, and colorectal cancer.

27²9³2⁻³4³7⁴5⁴8⁵1⁵7⁻⁵8⁶5 However, published studies have limitations that preclude drawing definitive conclusions about the efficacy of patient navigation, such as lack of control groups, lack of randomization to treatment or comparison groups, low sample size, no single definition of patient navigation, and combining patient navigation services with other interventions. Thus, information about the efficacy of patient navigation programs is limited, and there is no information about cost-effectiveness of patient navigation.

The PNRP is a collaborative effort designed to overcome limitations in the research literature by evaluating efficacy and cost effectiveness of various models of patient navigation in cancer in a standardized rigorous process. The PNRP is collecting standardized data across nine sites to determine characteristics of successful and cost-effective navigation programs and which patients benefit from patient navigation. Until more information is available regarding the efficacy of patient navigation programs, institutions considering implementing such interventions should be aware of the paucity of data regarding such benefits.

To date, there are no formal recognized certification programs for patient navigators, nor is there evidence indicating which characteristics of navigators are most efficacious in improving cancer outcomes. Patient navigators have a variety of backgrounds and levels of formal education, and there is little information regarding training of navigators.21⁷³ The PNRP program has provided centralized standardized training to patient navigators from all nine sites and is collecting data to determine characteristics of navigators that predict better outcomes in abnormal screening tests as well as cancer diagnosis and treatment. If patient navigator training program and evaluate appropriateness of a formal certification process for patient navigators. Without such formal certification, it will be difficult to obtain reimbursement from insurance companies or the federal government for patient navigation services.

In conclusion, patient navigation is an intervention designed to reduce health disparities by addressing specific barriers to obtaining timely, quality health care. This intervention is used in many different settings to target various cancer outcomes in many different populations. Although published research indicates that patient navigation may be associated with improvements in screening and diagnostic resolution following screening in certain populations, the research limitations preclude drawing generalizable conclusions regarding

efficacy of patient navigation. A thorough evaluation of PNRP and other scientifically rigorous future programs is necessary to ensure that navigator programs are effective and cost-effective prior to continued dissemination.

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Table 1

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Citation	Cancer	Design	Participants, Location	Outcome Measures	Results
Cancer Scr	Cancer Screening Studies				
Dignan et al., 200529	Breast	Prospective RCT (face-to-face navigator intervention, telephone navigator intervention, control)	157 Native American women, Denver, Colorado	Adherence to mammography screening guidelines.	Participants in either intervention group more likely to receive mammography according to guidelines after intervention than before intervention. Telephone intervention more effective than face-to-face intervention.
Fang et al., 200735	Cervical	Prospective comparison of cervical cancer screening intervention plus patient navigation or control group that received 2 hour general health education session	Korean American women (50 in control group; 52 in intervention group)	Difference between intervention and control in receipt of pap screening at follow up.	39 of 52 intervention participants requested navigation services. Intervention participants more likely to receive pap smear than control participants (p <.001).
Jandorf et al., 200545	Colorectal	Prospective RCT (patient navigation or control)	40 participants in control group; 38 participants received patient navigation, East Harlem, New York	Colorectal cancer screening adherence	1. At 3-month chart review more patient navigation participants scheduled endoscopy appointments (p =.005) 2. At 6-month chart review, more patient navigation patients had completed an endoscopy (p <.02)
Nash et al., 200648	Colorectal	Retrospective, comparison of patients who received care before and after patient navigator plus gastrointestinal suite improvement intervention.	1,767 patients who received diagnostic or screening colonoscopies either before on after intervention; Patients who completed preadmission testing. Bronx, New York	 Rate of colonoscopies Rate of broken appointments 	 Increase in number of people who received screening colonoscopies. Broken appointment rate declined from 67.2% to 5.3%.
Rahm et al., 200752	BRCA1/2 genetic counseling	Prospective RCT	125 participants referred for genetic counseling, Kaiser Permanente, Colorado	 Genetic counseling participation within 9 months of referral Time from referral to completed genetic counseling appointment. 	 No significant difference in appointment attendance between navigation and usual care. Not enough power to detect differences. Patient navigator intervention participants had appointments scheduled significantly sooner than usual care participants.
Tingen et al., 199857	Prostate cancer	Prospective RCT. Sites randomized to traditional prostate cancer education, peer- only, client-navigator only, or combination of peer- educator and client-navigator.	1522 participants in a prostate cancer screening program, southeastern state	Participation in free prostate cancer screening.	In multiple logistic regression, participants who received either client navigation intervention or combined intervention more likely to participate in screening program than prostate cancer education participants.
Weinrich et al., 199858	Prostate cancer	Prospective RCT. Sites randomized to traditional prostate cancer education, peer- educator only, client-navigator only, or combination of peer-	1717 participants in a prostate cancer screening program, southeastern state	Participation in free prostate cancer screening.	African-American and total study participants who received either client navigation or peer education intervention more likely to participate in screening program than traditional intervention participants. Participants who received education alone were as

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Citation	Cancer	Design	Participants, Location	Outcome Measures	Results
		educator and client-navigator.			likely to participate in screening as combined peer education and client navigation intervention participants.
Cancer Car	Cancer Care Following Abnormality	bnormality			
Battaglia et al., 200727	Breast	Retrospective comparison of women seen before and after navigation intervention	1332 women with abnormal screening, Boston, Massachusetts	Timely follow up from referral to diagnostic resolution	Navigation participants more likely to have timely follow-up than participants screened before intervention. Intervention effect remained after (1) controlling for race, age, insurance status, reason for referral and source of referral; and (2) using propensity score analysis to adjust for differences in pre and post intervention samples.
Ell et al., 200232	Breast	Prospective, study enrollees compared to non-enrollees. Intervention included health education, navigation, and counseling	Women who received abnormal mammograms. 605 participants were compared to 695 nonenrollees, Los Angeles, California; and New York, New York.	 Adherence to follow up care following abnormal mammogram. Timeliness of diagnostic resolution. Timeliness of initiation of cancer treatment. 	 Intervention participants more likely to adhere to follow up recommendations than non-enrollees. Enrollees more likely to get to diagnostic resolution in a timely manner than non-enrollees. Non statistically significant difference in timeliness of initiation of cancer treatment between enrollees and nonenrollees.
Ell et al., 200233	Cervical	Prospective, study enrollees compared to non-enrollees. Intervention included health education, navigation, and counseling	Women with low grade and high grade squamous intraepithelial lesions prescribed follow up repeat screening. 196 women enrolled in study compared to 369 non-enrollees, Los Angeles, California	Adherence to follow up appointments.	Intervention participants had significantly better rates of adherence to at least one follow up appointment $(p=.0002 \text{ and } p=.0001)$.
Ell et al., 200734	Breast	Prospective RCT (patient navigation plus counseling or usual care)	Women who received abnormal mammograms (96 in intervention group, 108 in control group), Los Angeles, California	 Adherence to diagnostic follow up through diagnostic resolution. Timely adherence from index screen to diagnostic resolution Timely entry rates for cancer patients. 	 Intervention group participants more likely to adhere to diagnostic follow up than usual care participants or women who did not participate in study. Intervention group participates had more timely adherence than usual care participants and non- participants. Intervention participants diagnosed with cancer were more likely to have timely entry rates (diagnosis, treatment) than usual care participants.
Ferrante et al., 200865	Breast	Prospective RCT (usual care or usual care plus patient navigation)	Women with suspicious mammogram results (BIRADS 4 or 5), 50 participants assigned to usual care, 55 participants assigned to usual care plus patient navigation. Newark, New Jersey	 Time from abnormal mammogram to date of diagnostic resolution. Differences in anxiety and satisfaction between usual care and intervention groups 	1. Mean diagnostic interval less in intervention group than usual care $(p=.001)$ 2. One month after diagnostic resolution, anxiety lower and satisfaction higher in intervention group when compared to usual care $(p<.001)$.

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Citation	Cancer	Design	Participants, Location	Outcome Measures	Results	
Freeman et al., 199537	Breast, cervical, prostate, colorectal	Prospective, patients who received navigation compared to patients who did not receive navigation	 Patients with an abnormal screening test for breast, cervical, prostate, or colorectal cancer (n=1136). Patients with cancer (n=8). Harlem, New York. 	 Whether participants obtained a biopsy following a suspicious/abnormal finding. Amount of time to complete biopsy. 	1. Non significant finding that 85.7% of navigated patients obtained a biopsy whereas 56.5% of non-navigated patients completed a biopsy. 2.71.4% of navigated patients completed biopsy in less than 4 weeks whereas 38.5% of non-navigated patients completed the biopsy in less than 4 weeks $(p=.047)$	
Giese- Davis et al., 200641	Breast	Prospective, pre-post comparison of navigation participants	29 women recently diagnosed with breast cancer, Santa Cruz, California	Change over time (baseline, three months, six months, nine months) in depression, trauma symptoms, desire for information on breast cancer, emotional and social quality of life, self-efficaecy to cope with cancer, and doctor-patient relationship	Trauma symptoms and desire for breast cancer resource information decreased and emotional well-being and cancer self-efficacy increased.	
Nash et al., 200648	Colorectal	Retrospective, comparison of patients who received care before and after patient navigator plus gastrointestinal suite improvement intervention.	1,767 patients who received diagnostic or screening colonoscopies either before or after intervention; Patients who completed preadmission testing. Bronx, New York	 Rate of colonoscopies Rate of broken appointments 	 Increase in number of people who received screening colonoscopies. Broken appointment rate declined from 67.2% to 5.3%. 	
Oluwole et al., 200363	Breast	Retrospective, comparison of patients who received care before and after intervention that included patient navigation, free cancer screening, and health education	12,480 patients seen following intervention implementation from January 1995 to December 2000; 324 patients diagnosed with breast cancer. Comparison group received care from 1964 to 1986. Harlem, New York	1. Stage at diagnosis 2. Survival	1. Reduction in late stage (III and IV) disease at presentation, from 49% before intervention to 21% after intervention (p <.001). 2. Significant increase in early stage diagnosis (0 and 1), from 6% before intervention to 41% after intervention (p <.001). 3. Crude 5-year survival rate of patients treated after intervention was 70.2%, compared with 39% 5-year survival rate of women with surgically treated cancer before intervention	
Psooy et al., 200451	Breast	Retrospective, comparison of patients who received care before and after patient navigation program	536 patients who underwent core breast biopsy. Nova Scotia, Canada	Time from screening abnormality to diagnostic resolution.	Patient navigator intervention participants had significantly less time from screening abnormality to biopsy $(p<.001)$.	
RCT=randor	RCT=randomized controlled trial	d trial				

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