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## Patient Navigation: An Update on the State of the Science

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### Abstract

Although patient navigation was introduced two decades ago, there remains a lack of consensus regarding its definition, qualifications of patient navigators, and impact on the continuum of cancer care. This review provides an update to Wells et al.'s 2008 review on patient navigation. Since then, there has been a significant increase in the number of published studies dealing with cancer patient navigation. The authors of the current review conducted a search by using keywords "navigation" or "navigator" and "cancer." Thirty-three articles published from November 2007 through July 2010 met the search criteria. Consistent with the prior review, there is building evidence of some degree of efficacy in patient navigation in terms of increasing cancer screening rates. However, there is less recent evidence regarding the benefit of patient navigation in terms of diagnostic follow up and in the treatment setting. There remains a paucity of research focusing on patient navigation in survivorship. Methodological limitations were noted in many studies, including small sample sizes and lack of control groups. As patient navigation programs continue to develop across North America and beyond, future research will be required to determine the efficacy of cancer patient navigation across all aspects of the cancer care continuum.

### INTRODUCTION

Over the past two decades, cancer mortality rates have declined in the United States as a result of improved rates of screening, reductions in cancer risk factors, and more effective cancer treatments.<sup>1</sup> However, there remain significant disparities in cancer mortality by race and socioeconomic status.<sup>1, 2</sup> A number of factors contribute to these disparities, including social deprivation associated with low socioeconomic status; access to and quality of medical care; differences in cancer risk factors; differences in rates of cancer screening;

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biological factors; and environmental factors in terms of the contextual factors in the environment (e.g. where one lives, distance to healthcare resources, discrimination in the community, etc.).<sup>1-3</sup> All of these factors contribute to barriers in cancer care.

An intervention model, patient navigation, has been advocated as a possible approach to addressing barriers to cancer care.<sup>4-8</sup> Patient navigation is a “barrier focused intervention that has the following common characteristics: (1) Patient navigation is provided to individual patients for a defined episode of cancer-related care (e.g., evaluating an abnormal screening test); (2) Although tracking patients over time is emphasized, patient navigation has a definite endpoint when the services provided are complete (e.g., the patient achieves diagnostic resolution after a screening abnormality); (3) Patient navigation targets a defined set of health services that are required to complete an episode of cancer-related care; (4) Patient navigation services focus on the identification of individual patient-level barriers to accessing cancer care; and (5) 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 the number of patients lost to follow-up.”<sup>9</sup>

The term “patient navigation” was created by Dr. Harold P. Freeman, who partnered with the American Cancer Society (ACS) to create the first patient navigation program in Harlem, New York.<sup>8</sup> This patient navigation program provided assistance to low income women for the purpose of obtaining breast cancer screening and follow up care and was associated with a reduction in late stage breast cancer and an increase in early stage breast cancer.<sup>10</sup>

Since 1990, there has been a large expansion in patient navigation programs across the United States for cancer and other diseases. This expansion was related to increases in funding for the intervention model by the federal government and private foundations, such as the American Cancer Society, the Avon Foundation, and the Susan G. Komen Breast Cancer Foundation.<sup>11</sup> The federal government has supported three large initiatives related to patient navigation. Funded in 2005 by the National Cancer Institute’s Center to Reduce Cancer Health Disparities and the American Cancer Society (ACS), the Patient Navigation Research Program (PNRP) is a nine site clinical trial designed to provide information regarding the efficacy and cost-effectiveness of patient navigation.<sup>9, 12-14</sup> The Centers for Medicare and Medicaid Services (CMS) funded six four-year demonstration programs in 2006. These programs received funding through *Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities* of the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) Benefits Improvement and Protection Act of 2000.<sup>15</sup> In 2005, the Patient Navigator Outreach and Chronic Disease Prevention Act authorized demonstration programs to improve health outcomes for patients with cancer and other chronic diseases. Six two-year demonstration programs were funded by the Health Resources and Services Administration (HRSA) in 2008 to support lay patient navigators who provide services that focus on a wide variety of health conditions (e.g., cancer, heart disease, diabetes, hypertension, obesity, asthma).<sup>16</sup> Ten new patient navigation demonstration projects were funded by HRSA in 2010.<sup>17</sup>

In 2008, a literature review was published that identified and summarized both descriptive and efficacy literature on patient navigation.<sup>9</sup> Using a PubMed search, the previous review identified and reviewed 45 articles describing patient navigation programs related to cancer conducted in the United States and Canada.<sup>4, 6, 11, 18-60</sup> Sixteen of these articles provided data on the efficacy of patient navigation with most studies focused on improving outcomes for breast cancer<sup>8, 10, 61-67</sup> or other cancers for which a screening test was available (cervical,<sup>8, 68, 69</sup> colorectal,<sup>8, 40, 70</sup> prostate<sup>8, 71, 72</sup>).

The literature review revealed that patient navigation programs were being implemented for both medically underserved populations and general medical populations, and were delivered by patient navigators with multiple educational backgrounds (e.g., lay navigators, nursing, social workers, health educators, cancer survivors). There was evidence of the efficacy of patient navigation in improving screening rates for 3 cancers, with improvements in the rate of screening ranging from 10.8% to 17.1%. In addition, there were improvements in adherence to follow up visits following a screening abnormality ranging from 21% to 29.2% and in timeliness of resolving a screening abnormality for patients screened for breast, cervical, colorectal, or prostate cancers. There was less information regarding whether patient navigation was associated with reductions in late stage cancer diagnoses, or improvements in cancer treatment outcomes, cancer survivorship, and psychosocial outcomes, including patient satisfaction. There were a number of methodological weaknesses noted in the studies reviewed, including low sample sizes, lack of randomized controlled trials to assess the efficacy of navigation, and combining patient navigation with other intervention components, such as counseling.<sup>9</sup>

Since 2008, many additional patient navigator programs have been implemented, and several additional research studies have been conducted to evaluate the efficacy of patient navigation interventions. The objective of the present literature review is to identify and summarize both descriptive and efficacy literature on patient navigation published since the previous literature review was conducted in 2008 and to provide a summary on the state of patient navigation to date.

## METHODS

A review of the literature in the National Library of Medicine was completed using a search via the PubMed database for articles on cancer patient navigation. The search parameters for this review follow those for Wells et al.'s 2008 review.<sup>9</sup> The search was conducted with the following inclusion parameters: articles published in the English language; articles involving human research participants; and articles published from November 2007 through July 2010. Further, in order to be included in this review, articles needed to have been original studies reporting quantitative, qualitative, or mixed methods results regarding patient navigation dealing with cancer screening, diagnosis, treatment, clinical trials, or survivorship. Editorials, literature reviews, and articles lacking data from an original research study were excluded from this review. The keywords "navigation" or "navigator" and "cancer" were used for this search. A total of 255 citations resulted from this search, of which 42 referenced cancer patient navigation as previously described.<sup>9, 13, 14, 27, 53, 73–109</sup> Twenty-three citations met the criteria to be included in this review.<sup>74, 76–79, 81–84, 86, 87, 90–93, 95, 97, 99, 100, 102, 103, 105, 107, 108</sup> An additional 10 articles were identified independently of the PubMed search that fit the inclusion criteria for purposes of this review.<sup>110–119</sup> Therefore, a total of 33 articles met the search criteria and are included in this review.

The articles were reviewed and summarized by one study author (JPH). Questions regarding inclusion were resolved by consensus among the other two authors (EDP & KJW). Each article was reviewed and information regarding the design and results of the study was summarized in tables.

## RESULTS

Condensed results from a review of all studies are presented in Tables 1 and 2. Table 1 comprises a summary of published cancer patient navigator efficacy studies (N=17); Table 2

provides a summary of published cancer patient navigator descriptive and qualitative studies (N=16).

### **Heterogeneity of Patient Navigators**

The recent literature shows continued variance in the type of personnel providing cancer patient navigation. Patient navigator backgrounds vary from case managers<sup>79</sup> and social workers<sup>81</sup> to tumor registrars<sup>97</sup> and breast cancer patients.<sup>115</sup> In most articles, patient navigators were either nurses,<sup>84, 102, 107, 117</sup> or lay/community health workers.<sup>86, 91, 103</sup> Multiple studies noted the importance placed on ensuring that patient navigators were trained in terms of cultural and linguistic capacities appropriate to the population served.<sup>77, 90, 103</sup> The majority of patient navigators were compensated for their efforts as opposed to being volunteers.

### **Populations Served by Patient Navigators**

The overwhelming majority of patient navigator programs studied were targeted towards patient populations at higher risk of not receiving adequate cancer care services, due to cultural, economic, geographic, or social disparities. Several research efforts focused on underserved urban patient populations<sup>77, 87, 102</sup> while some dealt with underserved rural populations, particularly the Native American population.<sup>90, 93, 97</sup> Minority patient populations were included in a large number of studies<sup>77, 78, 81, 86, 87, 90, 91, 93, 99</sup> as were low-income populations.<sup>78, 83, 86</sup> However, several studies of patient navigation programs not expressly focused on underserved patient populations were also conducted and included in this review.<sup>76, 84, 100, 107, 114, 118</sup>

### **International Patient Navigation**

Two qualitative articles reported the findings of patient navigation studies conducted outside of the United States and Canada (Table 2).<sup>82, 118</sup> One international study evaluated cancer care coordination from the perspectives of patients and their caregivers (i.e. spouse, child) in Australia. The major finding of this qualitative work was the identification of “seven key components” to cancer care coordination: (1) organization of care; (2) access to and navigation through the system; (3) patient navigator as a “key contact” person; (4) communication and coordination among a multidisciplinary team; (5) timely rendering of services; (6) provision of information to the patient; and (7) patient needs assessment.<sup>118</sup>

The second international study highlighted the fragmented manner in which breast cancer patients in Ethiopia are referred for cancer care. The “navigation chains” patients traversed involved multiple and divergent nodes of care, including traditional healers. The conclusion of the study was that streamlined efforts were needed for improved access to breast cancer screening, diagnosis, and treatment services recommendations that point—to the potential benefit provided by cancer patient navigators.<sup>82</sup>

### **Patient Navigation in the Continuum of Care**

Comparable to the 2008 review, the recent studies in cancer patient navigation focus on improving care across the breadth of the cancer care continuum. In the present review, articles centered on cancer screening rates;<sup>77–79, 91, 95, 99, 100, 103, 110, 119</sup> cancer diagnosis outcomes;<sup>79, 82, 86, 87, 102, 110, 111</sup> cancer treatment outcomes;<sup>76, 83, 84, 92, 104, 112, 116, 117</sup> and clinical trials enrollment.<sup>90, 114</sup> One qualitative study identified the desire patients expressed for patient navigation services throughout the continuum of care, including into long-term survivorship.<sup>81</sup> However, no efficacy studies to date have published results of the effects of patient navigation on cancer survivorship outcomes.

## Efficacy of Patient Navigation

**Screening**—The majority of efficacy studies tested the impact patient navigation had on screening rates for breast, cervical or colorectal cancer (CRC).<sup>78, 79, 91, 95, 99, 103, 110, 119</sup> Six studies reported the difference in cancer screening rates between intervention and control groups as significantly favoring patient navigation;<sup>79, 91, 95, 99, 103, 119</sup> one study reported mammography annual rescreening rates of 55% for the intervention group compared with 1.5% for the control group in a medically underserved population of female patients (45% Latina; 34% Native American; 12% Caucasian; 9% African American).<sup>110</sup> Two randomized controlled trials (RCTs) evaluated the effectiveness of patient navigation programs for increasing CRC screening in predominantly Latino and Caucasian patient populations. One of these was a small pilot study (n = 34) in which compliance with screening colonoscopy among participants receiving patient navigation services was 54% while 13% of the control group completed screening colonoscopy (p=.058).<sup>78</sup> The second and more robust randomized controlled trial involved over 1200 patients randomized to either patient navigation (by telephone) or usual care (education materials). This study reported screening rates of 27% for the intervention group compared to 12% for the control group (p<.0001).<sup>103</sup>

These results suggest that patient navigation impacts cancer screening in a favorable manner as participants who received assistance from patient navigators in these studies were significantly more likely to complete cancer screening when compared to those who did not receive navigation. However, it is important to note that four of these eight studies focused on colorectal cancer screening;<sup>78, 95, 99, 103</sup> three focused on breast cancer screening;<sup>79, 91, 110</sup> and one focused on cervical cancer screening.<sup>119</sup> Additionally, while the collective study populations are broadly represented by African Americans, Latinos, Korean Americans, Chinese Americans, Caucasians, etc., in low income and medically underserved populations, each study population and setting was unique; therefore, the results may be limited in terms of generalizability across populations and across cancer types.

**Diagnostic Follow Up**—The only efficacy study during the time period reviewed that dealt with diagnostic resolution of abnormal cancer screenings was a prospective cohort study among 437 African American women in Boston, MA.<sup>79</sup> Clark et al. reported that timely follow up for abnormal results from screening mammograms was achieved by 85% of the study participants; however, this was not attributed to the navigation intervention but was more strongly correlated to insurance coverage and site level factors (HR 0.95, 95% CI 0.50–1.80; comparing baseline with post-navigation follow-up rates).<sup>79</sup>

**Stage at Diagnosis**—The sole efficacy study that focused on improving the proportion of patients diagnosed at an early cancer stage was a study of 487 women diagnosed with breast cancer at a public hospital in Atlanta, Georgia. The results of this study showed an increase in the proportion of patients diagnosed at stage 0 from 12.4%, measured prior to the implementation of the patient navigation intervention, to 25.8% (p<.005), measured after the implementation of the patient navigation. Similarly, there was a reduction in the proportion of patients diagnosed at stage IV from 16.8% before the patient navigation intervention was implemented to 9.4% (p<.05) after the intervention. However, this study involved outreach initiatives in the community, in addition to patient navigation, hence it is difficult to ascertain to what degree patient navigation was attributable to the changes in stage at diagnosis.<sup>87</sup>

**Treatment Outcomes**—Seven studies, including two RCTs,<sup>83, 117</sup> focused on the efficacy of patient navigation in improving cancer treatment outcomes<sup>83, 84, 105, 107, 112, 116, 117</sup> and presented mixed results. In a large RCT, Ell et al. found no statistical difference in treatment adherence rates for low-income, predominantly

Latina women with breast and gynecological cancer in which the control group received written information and the intervention group received patient navigation in addition to written materials; however, treatment adherence was high in both the navigation and control groups.<sup>83</sup> Skrutowski et al. discovered no significant differences in outcomes in measures for distress, fatigue, quality of life, and healthcare utilization for lung and breast cancer patients in a population consisting of female, predominantly financially secure, Canadian patients (approximately half French speaking, half English speaking) who received usual care and pivot nurse services (the Canadian pivot nurse position was described comparably to an American patient navigator).<sup>117</sup>

Five of these studies did not find any significant differences between navigated patients and usual care patients<sup>83, 107, 112, 116, 117</sup> across a variety of outcome measures, including treatment adherence rates among a population of low-income, predominantly Latina women;<sup>83</sup> radiation treatment completion (measured in days) among an underserved patient population;<sup>116</sup> distress, fatigue, quality of life and healthcare utilization among a female, predominantly financially secure, Canadian patient population;<sup>117</sup> and change in distress scores between admission and discharge among a population of hospitalized inpatients in the Midwest.<sup>107</sup>

Of the two efficacy studies that reported a significant difference in treatment outcomes with validated instruments, one found patient satisfaction ( $p=.03$ ) and emotional quality of life ( $p=.045$ ) were both significantly higher for head and neck cancer patients in a predominantly male, Canadian patient population receiving patient navigation; findings regarding hospital utilization, however, were mixed.<sup>84</sup> The second treatment efficacy study reported that navigated patients had an average of three fewer days of interruption for radiation therapy ( $p=.002$ ) in a Native American patient population.<sup>105</sup> The results of the treatment efficacy studies, therefore, do not provide clear evidence of the benefit of patient navigation during the treatment phase of cancer care.

### What Navigators (Should) Do

The descriptive and qualitative studies (Table 2) provide particular insight into what it is that patient navigators do or should do. Jean-Pierre et al. qualitatively analyzed patient navigator interview data and categorized the tasks of patient navigation into two types of interventions: instrumental interventions and relationship interventions.<sup>113</sup> Instrumental interventions are task-oriented or logistic in nature, such as helping a patient find transportation to appointments or find information about their diagnosis. Relationship interventions, on the other hand, involve those efforts by the patient navigator that build and strengthen the interpersonal relationships between patient and provider.<sup>113</sup>

Davis et al. identified four emergent themes from patient interview data that nicely broaden and expand on what patient navigators do or should do: (1) patient navigators should address access to care needs; (2) patient navigators should address emotional and practical concerns; (3) patient navigators should address patient family concerns; and (4) patient navigators should be involved throughout the continuum of care—from diagnosis to survivorship.<sup>81</sup>

Understanding the barriers patient navigators address helps shed light on the type of work they do for cancer patients. Lin et al. sought to understand how patient navigators spend their time addressing different barriers patients face.<sup>97</sup> The most common three barriers patient navigators spent their time on were related to: (1) insurance and out-of-pocket expenses; (2) transportation issues; and (3) helping to manage the feeling and fear associated with cancer. The most time consuming barrier reported was financial concerns. Patient navigators spent on average 2.5 hours addressing barriers for each patient with whom they worked.<sup>97</sup>

Vargas et al. conducted a case study designed to illuminate the initial patient navigator programs.<sup>108</sup> They reported that the purpose of the first patient navigation programs was to reduce cancer disparities in care related to race and poverty, and this was accomplished by combining cultural sensitivity with aspects of disease management.<sup>108</sup>

## DISCUSSION

The past three years have produced a comparable quantity of work in the cancer patient navigation literature as have the previous years combined. Using the same search methodology as a previous review,<sup>9</sup> the present review identified 52 citations describing patient navigation programs designed to improve outcomes along the cancer care continuum. Of the 33 citations that met inclusion criteria, 17 provided data on the efficacy of a patient navigation program. Similar to the previous literature review, patient navigation was provided by professionals with multiple types of training and lay persons and to multiple medically underserved and general medical populations. While these articles reported patient perspectives and cancer care outcomes, none discussed the implications of patient navigation in terms of organizational outcomes. For example, the opportunity for organizations to pursue patient navigation among well-insured patient populations as a means to improving organizational outcomes such as increased market share and profit margin is clearly obvious, but the literature to date is silent in this regard.

A notable difference between this review and the prior review is an apparent increase in research on the processes comprising patient navigation. In the previous review, there were a number of descriptive reports of the processes of patient navigation, but little systematic research. The present review includes studies designed to evaluate what it is patient navigators “should” do from the patient perspective in addition to studies reporting how patient navigators spend their time and on what specific tasks. Such process-oriented research may be beneficial in improving patient navigation programs broadly. However, given the great heterogeneity in patient navigation programs, the applicability of process-oriented research may not be universally applicable.

In evaluating the results of the 2008 review and the present review, it is clear that the strongest evidence to date for the effectiveness of patient navigation is in improving cancer screening and outcomes related to cancer diagnostic services. Similar to the previous review, most studies providing evidence for the efficacy of patient navigation were designed to increase rates of cancer screening.<sup>78, 79, 91, 95, 99, 103, 110, 119</sup> In the previous review, there were six published articles that provided evidence indicating patient navigation was associated with increases in cancer screening for three cancers.<sup>9</sup> In both reviews, there were methodological limitations noted in several studies.

In evaluating the results of the previous and current reviews together, there is evidence of the potential of patient navigation in improving outcomes related to the diagnosis of cancer; however, little progress has been made since the last review. Only one efficacy study<sup>79</sup> was published during the review period that evaluated the efficacy of patient navigation provided to improve diagnostic outcomes (e.g. reduced time to diagnostic resolution or improved follow-up rates); two descriptive studies<sup>86, 102</sup> also focused on diagnostic follow up. While there were several studies evaluating the effect of patient navigation on cancer diagnostic outcomes reviewed in the 2008 article, many of the studies reviewed had methodological limitations.<sup>9</sup> Taken together, the two reviews indicate there is still a need to conduct high quality research evaluating the effectiveness of patient navigation in improving cancer diagnostic outcomes such as the reduction in cancer diagnostic delays and the reduction in patients lost to follow up. There are only two known studies evaluating whether patient navigation was associated with a shift in the stage of cancer diagnosis,<sup>47, 87</sup> but both studies

combine patient navigation with other interventions that may have contributed to reductions in late stage cancer.

Since 2008, there has been an increase in studies evaluating the efficacy of patient navigation on cancer treatment outcomes. Seven new studies have evaluated the effect of patient navigation on a variety of outcomes during cancer treatment; however, similar to the 2008 review,<sup>9</sup> the evidence for the efficacy of patient navigation in improving these outcomes was inconclusive. This could be due to a number of issues related to study designs or the fact that cancer patients may be able to obtain more resources and support during cancer treatment. There are currently no known studies evaluating the efficacy of patient navigation on outcomes during cancer survivorship.

The efficacy studies displayed in Table 1 arguably provide the most important information regarding the potential benefits of patient navigation. However, few of these studies utilized an RCT design, the best known and most widely accepted method of evaluating an intervention effect.<sup>78, 83, 103, 117</sup> Two of the RCT studies involved colorectal cancer screening (one of which was a pilot and, thus, is limited in terms of conclusive results), and two RCTs dealt with treatment in patients with breast, lung and gynecologic cancers. Some studies lacked large samples sizes and some lacked comparison groups, which limits the strength of the reported findings.

At this juncture we know several things about patient navigation that are relevant to clinicians in community practice. First, we know that patient navigation programs and the backgrounds of those who serve as patient navigators are diverse and appear to be driven by local needs. There is not one type of patient navigation model that fits the needs of all medical settings or systems. Therefore, if a clinician or health care organization is considering the implementation of a patient navigation practice, it is important to assess the needs of the populations served by that organization and tailor the intervention to those needs. Second, we know that patient navigation is provided both to underserved patients as well as to general patient populations. Third, we know that patient navigation is typically a goal-oriented intervention that focuses on reducing the barriers to achieving a particular cancer health care goal, such as improvements in cancer screening rates, cancer treatment adherence, or patient satisfaction with care. Clinicians or health care organizations who are considering the implementation of a patient navigation intervention should focus the intervention on making improvements to a particular outcome of interest. Fourth, while individual patients may find benefit from actions taken by patient navigators at various times across the cancer continuum, currently the literature on the effectiveness of patient navigation is strongest for interventions which targeted cancer screening outcomes.

Despite the dramatic increase in the number of published studies in patient navigation and patient navigation programs in the recent years, there is much we still do not know about cancer patient navigation. Although individual patients may benefit from the services of a patient navigator provided at any point in the cancer continuum, the cumulative evidence indicates that cancer screening rates for a population can be improved through well-designed patient navigation programs—these are the strongest results of patient navigation studies to date. However, in terms of diagnostic care, treatment, clinical trials recruitment and retention, and survivorship outcomes, there exists a great need for well-designed, well-powered controlled trials. Further, as the strongest results are for cancer screening, there exists a need for more work regarding the impact of patient navigation for cancers for which screening tests are not presently available.

In contemplating the potential benefits of cancer patient navigation, it is important to consider the perspectives held by the patients themselves. Patients reported that patient

navigators are effective in that they provide emotional support, information and problem-solving assistance, and logistical assistance.<sup>111</sup> However, in addition to the voice of the patient, future research should seek to incorporate the perspective of cancer care providers so as to increase the likelihood that patient navigation programs are designed and implemented in a sustainable manner. Continued and increased research on the impact of patient navigation on patient surrogates and loved ones is likewise warranted.

It is hoped that results from the newest patient navigation research programs, the large government-sponsored studies, will provide much needed information in the areas still understudied and for which strong evidence is lacking. If this evidence substantiates patient navigation then future work should examine the organizational strategies needed to incorporate patient navigation into healthcare settings, explore reimbursement methods, and establish competency-based training programs for patient navigation. Furthermore, ways of measuring the impact of these programs on mortality rates—especially among underinsured and minority populations—must be assessed on an ongoing basis. Thus, to have the greatest impact patient navigation must be efficacious, disseminated, institutionalized widely, with reimbursement mechanisms and training programs, and continually monitored and re-evaluated, as necessary. Moreover, the purpose of patient navigation—to overcome both relationship and instrumental barriers to care—should be stressed. Thus, while patient navigation shows great promise to reduce cancer health disparities, much still needs to be done to assess and implement the best functioning programs widely to realize this goal.

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**Table 1**

Summary of Published Cancer Patient Navigation Efficacy Studies: 2007–2010

Citation	Cancer	Continuum	Design	Participants (Location)	Outcome Measures	Results
Burhansstipano v 2010	Breast	Screening	Natural experiment; due to a change in legal policy, undocumented immigrants were not allowed to receive services at a certain point during the study period; those served prior to this change are compared to those after the change was implemented, the latter acting as a quasi-control group	313 medically underserved female patients (45.4% Latina; 33.9% Native American; 12.2% Caucasian; 8.6% African American); 113 received intervention, 200 did not receive intervention (Denver, CO)	Mammography annual rescreening rates	Statistically significant difference ( $p<.05$ ) found between patients receiving intervention and reporting receiving annual rescreening mammograms (55%) and those not receiving the intervention and reporting having had annual rescreening mammograms (1.5%)
Han 2009	Breast	Screening	Cohort study; compared baseline and post-intervention measures	100 Korean American women (Maryland)	Breast cancer screening rates	Breast cancer screening rates significantly increased at 6 months ( $p<.001$ ); 31.9% increase in mammography, 23% for clinical breast exam, 36.2% for breast self exam
Wang 2010	Cervical	Screening	Two-arm, quasi-experimental pilot study; intervention group received education, navigation, exposure to Chinese physician; control group received education and information about sites providing free screenings	134 Chinese American female participants (54 in the control group; 80 in the intervention group) (New York City, NY)	Cervical cancer screening rates	12 month post-intervention data show the intervention group screening rates were significantly higher than the control group rates (70% compared to 11%, $p<.001$ )
Chen 2008	Colorectal	Screening	Cohort study; patients referred by PCP for screening colonoscopy received patient navigation by telephone with limited in-person meetings	532 patients, mostly African American and Hispanic (New York City, NY)	Colonoscopy screening rates	66% of patients completed colonoscopy screening; women were 1.31 times more likely to complete colonoscopy than men ( $p=.014$ ); Hispanics were 1.67 times more likely than African Americans to complete colonoscopy ( $p=.013$ ); 66% reported they definitely or probably would not have completed colonoscopy without patient navigation

Citation	Cancer	Continuum	Design	Participants (Location)	Outcome Measures	Results
Christie 2008	Colorectal	Screening	Prospective RCT pilot study; intervention group received patient navigation and control group received usual care	21 participants (71% Hispanic; 21% African American; 8% other; 75% male); 13 received patient navigation (New York City, NY)	Compliance with screening colonoscopy	54% of the intervention group and 13% of control group completed screening colonoscopy (p=.058)
Lasser 2009	Colorectal	Screening	Cohort study; two community health centers, one where participants received navigation support for CRC screening after receiving letter from PCP (intervention) and one where participants received letter from PCP only (usual care)	93 participants in intervention group, 90 participants in control group; English, Portuguese, Spanish and Haitian Creole speaking patients; predominantly low-income (Somerville, MA)	Percentage of patients screened for CRC	31% of intervention patients screened at 6 months post intervention vs. 9% of usual care group (p<.001)
Ma 2009	Colorectal	Screening	Two group "quasi-experimental" design; intervention included education on CRC risks and patient navigation; control group received education only; baseline and 12 month follow-up data compared	167 Korean Americans (84 in intervention group; 83 in control group); predominantly low income (Pennsylvania)	Receipt of CRC screening (at baseline vs. 12 month follow up)	12 month follow-up data revealed 77% of intervention and 11% of control group received CRC screening (p<.001)
Percac-Lima 2009	Colorectal	Screening	RCT; intervention group received letter and educational materials and phone call from navigator; control group received usual care; 9 month study period	1,223 participants (age 52–79) due for CRC screening; 58% female; 47% Caucasian; 40% Latino; 5.5% African American; 2% Asian; 5% Other (Chelsea, MA)	CRC screening rates	Intervention group more likely to receive CRC screening (27% vs. 12% for control; p<.0001) and colonoscopy completion (21% vs. 10% for control; p<.001)
Clark 2009	Breast	Screening, Diagnostic Follow up	Prospective cohort study; case managers provided navigation to patients	437 African American women (Boston, MA)	Screening mammograms received and follow-up of abnormal screening results	Significant increase in screening uptake achieved (OR 1.53, 95% CI 1.13–2.08); timely follow up for abnormal results achieved by 85% of participants but not attributed to intervention (HR 0.95, 95% CI 0.50–1.80)
Gabram 2008	Breast	Stage at Diagnosis	Cohort study using historical data as control; aimed to determine if an outreach and navigation program measurably impacted stage at diagnosis	487 female participants (89% African American; 5% Caucasian; 2% Hispanic; 4% other) (Atlanta, GA)	Stage at diagnosis	Intervention resulted in statistically improved stage at diagnosis: stage 0 increased from 12.4% to 25.8% (p<.005) and stage IV decreased from 16.8% to 9.4% (p<.05)

Citation	Cancer	Continuum	Design	Participants (Location)	Outcome Measures	Results
Donelan 2010	Breast	Treatment	Cohort study; data from patients experiencing PN were compared to data from patients not experiencing PN	72 navigated patients, 181 non-navigated patients (Boston, MA)	Timeliness of care, preparation of patient for visit, ease of access, etc.	Instrument employed was not validated; most measures showed no difference between patients receiving navigation and those not receiving navigation
Elli 2009	Breast, Gyn	Treatment	Prospective RCT; control group received written information, intervention group received written information and patient navigation	487 low income (predominantly Hispanic) women (California)	Treatment adherence rates for completion of chemotherapy, radiation therapy, and hormone therapy	No significant differences in treatment adherence rates found between control and intervention groups; overall adherence rates ranged from 87% to 94%
Fillion 2009	Head and Neck	Treatment	Two independent cohorts of patients (one with navigation, one without) compared	83 patients (historical cohort) did not receive navigation; 75 patients (exposed cohort) received navigation (Canada)	Patient satisfaction, hospitalization (frequency and days), quality of life	Patients receiving navigation services reported higher overall satisfaction ( $p=.03$ ) and better emotional quality of life ( $p=.045$ ) compared to those in historical cohort; while the mean number of hospitalizations was significantly lower in the PN group ( $p=.003$ ) the total number of days hospitalized was not significantly different ( $p=.62$ ) between the historical and PN cohorts
Skrutkowski 2008	Lung, Breast	Treatment	RCT; patients randomly assigned to usual care or usual care plus a pivot nurse (navigator)	93 patients in intervention group, 97 in usual care; (Quebec, Canada)	Distress, fatigue, quality of life, hospital utilization	No differences between intervention and control groups
Petereit 2008	Multiple	Treatment	Retrospective cohort analysis of treatment interruptions for navigated and non-navigated patients	Native American participants (42 with navigator, 74 without navigator) (South Dakota)	Radiation treatment interruptions	Patients with navigators had on average 3 fewer days of treatment interruptions for radiation therapy ( $p=.002$ )
Schwaderer 2008	Multiple	Treatment	Retrospective cohort analysis of length of time from patient referral to treatment completion, comparing navigated and non-navigated patients	72 patients receiving radiation treatment formed a "disparities group" (38 of which received navigator services); disparities include participant living in subsidized housing, being a Medicaid recipient, etc. 157 participants without disparities did not receive navigation (New Castle, PA)	Radiation treatment completion (days)	No statistically significant differences were discovered between patients receiving navigation services and those not receiving navigation

Citation	Cancer	Continuum	Design	Participants (Location)	Outcome Measures	Results
Swanson 2010	Multiple	Treatment	Retrospective cohort study; chart reviews to collect admit/discharge distress scores-- compared navigator vs. non-navigator scores	55 cancer inpatients (Lincoln, NE)	Change in distress scores of adult oncology inpatients at admission vs. discharge	No statistical difference found in distress scores between patients who received navigation services and those who did not (p=.1046)

**Table 2**  
 Summary of Published Cancer Patient Navigation Descriptive and Qualitative Studies: 2007–2010

Citation	Cancer	Continuum	Design	Participants (Location)	Outcome Measures	Results
Myers 2008	Colorectal	Screening	Descriptive study; telephone calls to patients and mailed materials regarding CRC screening; 6 month follow-up	154 primary care patients age 50+ and eligible for CRC screening (Delaware)	Percentage receiving CRC screening	41% of study participants had CRC screening by 6 months post intervention; no control group
Palmieri 2009	Breast	Diagnostic Follow up	Descriptive study; health department workers collaborated with Mayo Clinic Cancer Center (Jacksonville, FL) navigator to refer underinsured patients for diagnostic services	447 female participants (Jacksonville, FL)	Time from screening to diagnosis	Time between screening abnormality detection and diagnosis was 60 days or less for 81% of the women for whom data were available (n=325), and 82% of women with BI-RADS scores of 4 or 5 received diagnosis within 60 days
Fouad 2010	Breast	Diagnostic Follow up	Descriptive study; patient navigation provided for women with breast cancer or an abnormal mammogram screening	147 female participants, predominantly underserved African Americans, with breast cancer or abnormal mammogram screenings (Alabama)	Percentage of patients keeping appointments	Study participants kept 93% of their appointments compared to cited adherence rates to diagnostic follow-up of an abnormal mammogram of 50%–81%; no control group
Dye 2010	Breast	Diagnosis, treatment	Qualitative; key informant interviews with breast cancer patients in Ethiopia were conducted	69 patients interviewed (Ethiopia)	Understand how breast cancer patients in Ethiopia successfully navigated to referral hospital for cancer treatment	"Navigation chains" of patients are divergent and involve multiple types of care, including traditional healers; care system needs to be streamlined in order to provide better access to breast cancer detection and treatment referral services
Carroll 2010	Breast, Colorectal	Diagnosis, treatment	Qualitative study; exit interviews with patients who participated in an RCT	35 newly diagnosed cancer patients (New York)	Examine how navigation impacts patient perception of care	Patients reported that navigators provided emotional support, information and problem-solving assistance, and logistical assistance
Campbell 2010	Multiple	Treatment	Cross sectional survey of patients and staff providing feedback regarding cancer center navigation program	48 patients (94% Caucasian; 6% African American; 54% Male) and 26 employees (Anderson, SC)	Patient satisfaction and staff agreement were measured	Findings showed that patients receiving navigation were more satisfied, however instrument was not validated; staff agreement with survey statements was reported
Howell 2008	Multiple	Treatment	Mixed methods evaluation; qualitative data were captured via semi-structured interviews and descriptive data were obtained from patient databases and charts	700 patients treated for cancer in a 12-month period (Ontario, Canada)	Reason for and source of referrals to nurse-led case management program; duration of time patient received service from program; evaluation of program by providers	40% of patients were in the program 0–2 months and 34% were in the program for 2–6 months; the remainder were in the program for over 6 months. 35% of referrals came from hospitals and 26% from self referrals. 68% of service providers indicated the specialized oncology

Citation	Cancer	Continuum	Design	Participants (Location)	Outcome Measures	Results
Guadagnolo 2009	Multiple	Clinical Trials	Prospective tracking of clinical trials enrollment in a program in which patients received navigation services	94 American Indian cancer patients (Rapid City, SD)	Percentage enrolled on clinical study	nurse role was very or extremely important in the provision of supportive services; providers reported referring patients to service primarily for psychosocial support (54%) and information assessment (40%) 10% of American Indians enrolled in a clinical trial; no control group
Moffitt 2010	Multiple	Clinical Trials	Mixed methods evaluation of statewide clinical trial navigation service	6,350 patient questionnaires were completed; semi-structured interviews conducted with various oncology professionals (Florida)	Patient awareness of and enrollment in clinical trials	The navigation system increased awareness of clinical trials but did not impact enrollment in clinical trials
Davis 2009	Breast	Full Continuum	Qualitative study; four focus groups conducted with breast cancer survivors	36 African American women (Tennessee)	Identify needs of underserved cancer patients and provide input on models of care	Four themes emerged: 1) patient navigators need to address access to care; 2) patient navigators need to address emotional and practical concerns; 3) patient navigators need to address family concerns; 4) patient navigators should be involved throughout continuum of care (from diagnosis to long-term survivorship)
Schlueter 2010	Breast	Full Continuum	Qualitative study; in-depth interviews conducted with breast cancer patients	18 breast cancer patients enrolled in patient navigation program in which patient navigators are breast cancer survivors (Atlanta, GA)	Evaluation of the Avon Foundation Community Education and Outreach Initiative Patient Navigation Program	Program strengths included the relationship with and availability of the patient navigator and patient navigators being breast cancer survivors. The major weakness related to enrollment in the program; patients found the enrollment process confusing and were not always aware if (and how) they were enrolled in the program
Jean-Pierre 2010	Breast, Colorectal	Full Continuum	Qualitative study of patient navigators' experiences providing navigation services for randomly assigned patients	21 transcripts of exit interviews with three navigators regarding their experiences with patients (Rochester, MN)	Accounts of navigators' experiences with cancer patients	Navigators provided two types of interventions: instrumental intervention (i.e. meeting insurance, transportation, information needs) and relationship intervention (i.e. making efforts to strengthen the navigator-patient and patient-clinician relationships)
Kanekar 2009	Multiple	Full Continuum	Descriptive report of a community-based participatory research program (Walking Forward) designed to lower cancer mortality	984 American Indians participated in community survey; 165 cancer patients, including 52 American Indians, participated in the cancer	Assess community perceptions and facilitate access for American Indians to clinical trials, behavioral and genetic	47% of respondents to the community survey identified transportation as a barrier; patient surveys showed that American Indian patients had significantly higher mistrust ( $p=0.001$ ) and lower satisfaction ( $p=$

Citation	Cancer	Continuum	Design	Participants (Location)	Outcome Measures	Results
Lin 2008	Multiple	Full Continuum	Descriptive study of the types of patient barriers and time navigators spend addressing various patient barriers, etc.; patients enrolled through hospital registry (after path report submitted, ordering physician was consulted regarding patient recruitment to study)	299 cancer patient participants (Pennsylvania)	Types of barriers to care, number of requests made by patients (and time spent by navigator) for assistance for each barrier type	The top three identified barriers include insurance and out of pocket expenses; transportation; and managing feelings/fear associated with cancer. Insurance and transportation requests for assistance were greatest, followed by requests for information and scheduling assistance. Navigators spent on average 2.5 hours addressing barriers for each patient. Most commonly reported and most time-consuming barrier was financial issues/concerns
Vargas 2008	Multiple	Full Continuum	Qualitative case study; semi-structured interviews, review of clinic documentation, etc.	Navigators and other staff of the first patient navigation site (Harlem Hospital) and two sites developed by same leadership team were interviewed (New York City, NY)	Provide a descriptive analysis of the initial patient navigation programs	The first navigation programs combined cultural and community sensitivity with elements of disease management to reduce disparities in care related to race and poverty
Walsh 2010	Multiple	Full Continuum	Qualitative study; semi-structured interviews and focus groups	20 cancer patients, 4 cancer patient caregivers (i.e. spouse, child), and 29 clinicians participated in this study (Australia)	Explore the experiences of cancer patients and providers as it relates to cancer care coordination	Seven key elements of cancer care coordination identified: organization of care, access to and navigation through healthcare system, allocation of 'key contact' person, communication and cooperation among multidisciplinary team and other providers, complementary and timely manner of service delivery, sufficient and timely information to the patient, and needs assessment