Patient Navigation: An Update on the State of the Science

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Abstract

Although patient navigation was introduced 2 decades ago, there remains a lack of consensus regarding its definition, the necessary qualifications of patient navigators, and its impact on the continuum of cancer care. This review provides an update to the 2008 review by Wells et al 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 the 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 of patient navigation in terms of increasing cancer screening rates. However, there is less recent evidence concerning the benefit of patient navigation with regard to diagnostic follow-up and in the treatment setting, and a paucity of research focusing on patient navigation in cancer survivorship remains. Methodological limitations were noted in many studies, including small sample sizes and a lack of control groups. As patient navigation programs continue to develop across North America and beyond, further research will be required to determine the efficacy of cancer patient navigation across all aspects of the cancer care continuum.

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Introduction

Over the past 2 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.1 However, there remain significant disparities in cancer mortality by race and socioeconomic status.1,2 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, biological factors, and contextual environmental factors (eg, where one lives, the distance to health care resources, discrimination in the community, etc).1-3 All of these factors contribute to creating barriers in cancer care.

An intervention model, patient navigation, has been advocated as a possible approach to addressing these barriers.4-8 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 (eg, 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 (eg, 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.9

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.8 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 the diagnosis of late-stage breast cancer and an increase in the diagnosis of early-stage breast cancer.10

Since 1990, there has been a large increase in the number of 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 ACS, the Avon Foundation for Women, and Susan G. Komen for the Cure.11 The federal government has supported 3 large initiatives related to patient navigation. Funded in 2005 by the National Cancer Institute’s Center to Reduce Cancer Health Disparities and the ACS, the Patient Navigation Research Program is a 9-site clinical trial designed to provide information regarding the efficacy and cost-effectiveness of patient navigation.9,12-14 The Centers for Medicare and Medicaid Services funded six 4-year demonstration programs in 2006. These programs received funding through Medicare’s Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities, Medicaid, and the State Children’s Health Insurance Program (SCHIP) Benefits Improvement and Protection Act of 2000.15 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 2-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 (eg, cancer, heart disease, diabetes, hypertension, obesity, and asthma).16 Ten new patient navigation demonstration projects were funded by HRSA in 2010.17

In 2008, a literature review was published that identified and summarized both descriptive and efficacy studies regarding patient navigation.9 Using a PubMed search, the previous review identified and reviewed 45 articles describing patient navigation programs related to cancer that were conducted in the United States and Canada.4-8,10,11,18-55 Sixteen of these provided data on the efficacy of patient navigation, with most studies focused on improving outcomes for patients with breast cancer8,10,18,21,23,24,27,33,44 or other cancers for which a screening test was available (cervical,8,25,26 colorectal,8,36,40 and prostate8,52,53 cancers).

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

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 the descriptive and efficacy literature concerning patient navigation published since the previous literature review was conducted in 2008 and to provide a summary of the state of patient navigation to date.

Material and Methods

A review of the literature in the National Library of Medicine was completed using a search of the
PubMed database for articles on cancer patient navigation. The search parameters for this review follow those for the review by Wells et al that was published in 2008. 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. Furthermore, to be included in this review, articles needed to have been original studies reporting quantitative, qualitative, or mixed methods results regarding patient navigation that dealt with cancer screening, diagnosis, treatment, clinical trials, or survivorship. Editorials, literature reviews, and articles lacking data from an original research study were excluded. The keywords “navigation” or “navigator” and “cancer” were used for this search. A total of 255 citations resulted, of which 42 referenced cancer patient navigation as previously described. A total of 23 citations met the criteria for inclusion in this review. Therefore, a total of 33 articles met the search criteria and are included in the current review.

The articles were reviewed and summarized by one study author (J.P.H.). Questions regarding inclusion were resolved by consensus among the other 2 authors (E.D.P. and K.J.W.). Each article was reviewed, and information regarding the design and results of the study is summarized in Tables 1 and 2.

Results

Condensed results from a review of all the 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 demonstrates continued variance in the type of personnel providing cancer patient navigation services. Patient navigator backgrounds vary from case managers and social workers to tumor registrars and breast cancer patients. In most of the articles examined, patient navigators were either nurses or lay/community health workers. 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. 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 toward 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, whereas some examined underserved rural populations, particularly Native Americans. Minority patient populations were included in a large number of studies as were low-income populations. However, several studies of patient navigation programs not expressly focused on underserved patient populations were also conducted and included in this review.

International Patient Navigation

Two qualitative articles reported the findings of patient navigation studies conducted outside of the United States and Canada (Table 2). One international study evaluated cancer care coordination from the perspectives of patients and their caregivers (ie, 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) the 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.

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 study concluded that streamlined efforts were needed to improve access to breast cancer screening,
### TABLE 1. Summary of Published Cancer Patient Navigation Efficacy Studies: 2007–2010

| STUDY | CANCER | CONTINUUM | DESIGN | PARTICIPANTS (LOCATION) | OUTCOME MEASURES | RESULTS |
|-------|--------|-----------|--------|-------------------------|------------------|---------|
| Burhansstipanov 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 were compared with those served 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, and 8.6% African American); 113 received intervention and 200 did not receive intervention (Denver, CO) | Mammography annual rescreening rates | Statistically significant difference (P < .05) found between patients receiving the intervention and reporting receiving annual rescreening mammograms (55%) and those not receiving the intervention and reporting having had annual rescreening mammograms (13.5%) |
| Han 2009 | Breast | Screening | Cohort study; compared baseline and postintervention measures | 100 Korean American women (MD) | Breast cancer screening rates | Breast cancer screening rates significantly increased at 6 mo (P < .001); 31.9% increase in mammography, 23% for clinical breast examination, 36.2% for breast self-examination |
| 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 and 80 in the intervention group) (New York City, NY) | Cervical cancer screening rates | 12-mo postintervention data demonstrated the intervention group screening rates were significantly higher than the control group rates (70% compared with 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 |
| 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, and 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; 2 community health centers, one in which participants received navigation support for CRC screening after receiving letter from PCP (intervention) and one in which participants received letter from PCP only (usual care) | 93 participants in intervention group and 90 participants in control group | Percentage of patients screened for CRC | 31% of intervention patients screened at 6 mo after 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-mo follow-up data compared | 167 Korean Americans (84 in intervention group and 83 in control group); predominantly low income (Somerville, MA) | Receipt of CRC screening (at baseline vs 12-mo follow-up) | 12-mo follow-up data revealed 77% of intervention group and 11% of control group received CRC screening (P < .001) |
| Percac-Lima 2009 | Colorectal | Screening | RCT; intervention group received letters, educational materials, and telephone call from navigator; control group received usual care; 9-mo study period | 1223 participants (aged 52-79 y) due for CRC screening; 58% female; 47% Caucasian, 40% Latino, 5.5% African American, 2% Asian, and 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) |
| STUDY | CANCER          | CONTINUUM                    | DESIGN                                                                 | PARTICIPANTS (LOCATION)                                                                                                                                                                                                                                                                                                                                 | OUTCOME MEASURES                                                                 | RESULTS                                                                                                                                                                                                                                                                                                                                 |
|-------|-----------------|------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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, and 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)                                                                                                               |
| Donelan 2010 | Breast         | Treatment                    | Cohort study; data from patients experiencing patient navigation were compared with data from patients not experiencing patient navigation | 72 navigated patients and 181 non-navigated patients (Boston, MA)                                                                                                                                                                                                                                                                                           | Timeliness of care, preparation of patient for visit, ease of access, etc                             | Instrument used was not validated; most measures showed no difference between patients receiving navigation and those not receiving navigation                                                                                                                                   |
| Ell 2009    | Breast, gynecological | Treatment                    | Prospective RCT; control group received written information; intervention group received written information and patient navigation | 487 low-income (predominantly Hispanic) women (CA)                                                                                                                                                                                                                                                                                                      | 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 d), quality of life                                | Patients receiving navigation services reported higher overall satisfaction (P = .03) and better emotional quality of life (P = .045) compared with those in historical cohort; although the mean number of hospitalizations was significantly lower in the patient navigation group (P = .001), the total number of d hospitalized was not significantly different (P = .62) between the historical and patient navigation 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 and 97 in usual care (Quebec, Canada)                                                                                                                                                                                                                                                                                 | Distress, fatigue, quality of life, hospital utilization                                             | No differences between intervention and control groups                                                                                                           |
| Petereit & Burhansstipanov 2008 | Multiple | Treatment                    | Retrospective cohort analysis of treatment interruptions for navigated and non-navigated patients | Native American participants (42 with navigator, 74 without navigator) (SD)                                                                                                                                                                                                                                                                              | Radiation treatment interruptions                                                                       | Patients with navigators had on average 3 fewer d 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 whom received navigator services); disparities included participant living in subsidized housing, being a Medicaid recipient, etc. 157 participants without disparities did not receive navigation (New Castle, PA) | Radiation treatment completion (d)                                                                   | No statistically significant differences were discovered between patients receiving navigation services and those not receiving navigation services                                                                                                                     |
| Swanson & Koch 2010 | Multiple | Treatment                    | Retrospective cohort study; chart reviews to collect hospital admittance/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)                                                                                                                   |

PCP indicates primary care physician; RCT, randomized controlled trial; CRC, colorectal cancer; OR, odds ratio; 95% CI, 95% confidence interval; HR, hazard ratio.
### Table 2. Summary of Published Cancer Patient Navigation Descriptive and Qualitative Studies: 2007–2010

| Study | Cancer Type | Continuum | Design | Participants’ Location | Design | Participants | Recruitment Details | Outcome Measures | Results |
|-------|-------------|-----------|--------|-------------------------|--------|-------------|---------------------|-----------------|---------|
| Myers 2008 | Colorectal | Screening | Descriptive study, telephone calls to patients followed by mailed materials regarding CRC screening | 154 primary care patients aged 50 y and eligible for CRC screening (DE) | Screening | 44% | Percentage receiving CRC screening | Time from screening to diagnosis | 41% of study participants had CRC screening by 6 mo after intervention; no control group |
| Paskett 2008 | Breast | Diagnostic follow-up | Descriptive study, health department workers collaborated with Mayo Clinic Cancer Center to reach underinsured patients for diagnostic services | 447 female participants (Jacksonville, FL) | Follow-up | Percentage of patients keeping appointments | Understand how breast cancer patients in Rochester successfully navigated to medical care | Examined how navigation impacts patient perception of care | Patients reported that navigation provided emotional and logistical assistance; care system needs to be streamlined to provide better access to breast cancer detection and treatment referral services |
| Fouad 2009 | Breast, colorectal | Multiple | Qualitative study, key informant interviews with breast cancer patients in Ethiopia | 35 newly diagnosed cancer patients who participated in a RCT | Qualitative | Percentage enrolled on clinical trials | Examine how navigation impacts program duration of time patient received service from program; evaluation of program by providers | Reasons for and source of referrals were captured via semistructured interviews and descriptive data were obtained from patient databases and charts | The navigation system increased awareness of clinical trials but did not impact enrollment in clinical trials |
| Campbell 2010 | Breast | Treatment | Cross-sectional survey of patients and staff providing feedback on cancer center navigation program | 700 patients treated for cancer in a 12-mo period (Kansas, Canada) | Treatment | Percentage enrolled on clinical trial | Patient awareness of and treatment in clinical trials | Patient awareness of and treatment in clinical trials | Identifies needs for professional cancer patient and provider input on models of care |
| Howell 2009 | Breast, colorectal | Multiple | Mixed methods evaluation, qualitative data and descriptive data were obtained from patient databases and charts | 94 Native American cancer patients | Mixed methods evaluation | Percentage enrolled on clinical trial | Qualitative study, focus groups were conducted with breast cancer survivors | Qualitative study, focus groups were conducted with breast cancer survivors | Identifies needs for professional cancer patient and provider input on models of care |
TABLE 2. (Continued)

| STUDY           | CANCER          | CONTINUUM | DESIGN                                      | PARTICIPANTS (LOCATION)                                                                 | OUTCOME MEASURES                                                                 | RESULTS                                                                                                                                                  |
|-----------------|-----------------|-----------|---------------------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Schlueter 2010  | Breast          | Full      | Qualitative study; in-depth interviews      | 18 breast cancer patients enrolled in patient navigation program in which patient navigators are breast cancer survivors (Atlanta, GA) | Evaluation of the Avon Foundation for Women 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      | Qualitative study of patient navigators’ experiences providing navigation services for randomly assigned patients | 21 transcripts of exit interviews with 3 navigators regarding their experiences with patients (Rochester, MN) | Accounts of navigators’ experiences with cancer patients | Navigators provided 2 types of interventions: instrumental intervention (ie, meeting insurance, transportation, and information needs) and relationship intervention (ie, making efforts to strengthen the navigator-patient and patient-clinician relationships) |
| Kanekar & Petereit 2009 | Multiple | Full      | Descriptive report of a community-based participatory research program (Walking Forward) designed to lower cancer mortality rates among Native Americans in western SD. | 984 Native Americans participated in a community survey; 165 cancer patients, including 52 Native Americans, participated in the cancer patient survey (Rapid City, SD) | Assess community perceptions and facilitate access for Native Americans to clinical trials, behavioral and genetic research, and patient navigation | 47% of respondents to the community survey identified transportation as a barrier; patient surveys showed that Native Americans patients had significantly higher mistrust ($P = .0001$) and lower satisfaction ($P = .0001$) with health care compared with white patients; high accrual rates in clinical trials (25%) and a significant reduction in delays in radiation treatment were reported as results of patient navigation |
| Lin 2008 79     | Multiple        | Full      | Descriptive study of the types of patient barriers and time navigators spend addressing various patient barriers, etc; patients enrolled through hospital registry (after pathology report was submitted, ordering physician was consulted regarding patient recruitment to study) | 299 cancer patient participants (PA) | Types of barriers to care, number of requests made by patients (and time spent by navigator) for assistance for each barrier type | The top 3 identified barriers included 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 h addressing barriers for each patient. The most commonly reported and most time-consuming barrier was financial issues/concerns |
| Vargas 2008 80   | Multiple        | Full      | Qualitative case study; semistructured interviews, review of clinic documentation, etc | Navigators and other staff of the first patient navigation site (Harlem Hospital) and 2 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 100   | Multiple        | Full      | Qualitative study; semistructured interviews and focus groups | 20 cancer patients, 4 cancer patient caregivers (ie, spouse, child), and 29 clinicians participated in this study (Australia) | Explore the experiences of cancer patients and providers as they relate to cancer care coordination | Seven key elements of cancer care coordination were 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 |

CRC indicates colorectal cancer; BI-RADS, Breast Imaging-Reporting and Data System; RCT, randomized controlled trial.
diagnosis, and treatment services, recommendations that point to the potential benefit provided by cancer patient navigators.

Patient Navigation in the Continuum of Care

Comparable to the 2008 review by Wells et al, recent studies in cancer patient navigation have focused on improving care across the breadth of the cancer care continuum. In the present review, articles were centered on cancer screening rates, cancer diagnosis outcomes, cancer treatment outcomes, and clinical trial enrollment. One qualitative study identified the desire patients expressed for patient navigation services throughout the continuum of care, including into long-term survivorship. However, no efficacy studies to date have published findings regarding the effects of patient navigation on cancer survivorship outcomes.

Efficacy of Patient Navigation

Screening

The majority of efficacy studies tested the impact of patient navigation on screening rates for breast, cervical, or colorectal cancer (CRC). Six studies reported the difference in cancer screening rates between intervention and control groups as significantly favoring patient navigation; one study reported annual mammography rescreening rates of 55% for the intervention group compared with 1.5% for the control group (P = .058). The second and more robust RCT involved more than 1200 patients randomized to either patient navigation (by telephone) or usual care (educational materials). This study reported screening rates of 27% for the intervention group compared with 12% for the control group (P < .0001). These results suggest that patient navigation impacts cancer screening in a favorable manner because participants in these studies who received assistance from patient navigators were found to be significantly more likely to complete cancer screening when compared with those who did not. However, it is important to note that 4 of these 8 studies focused on CRC screening, 3 focused on breast cancer screening, and one study focused on cervical cancer screening. In addition, although 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 cancer types.

Diagnostic Follow-Up

The only efficacy study published during the time period reviewed that dealt with the diagnostic resolution of an abnormal cancer screening result was a prospective cohort study of 437 African American women in Boston. 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 with insurance coverage and site-level factors (hazard ratio, 0.95 [95% confidence interval, 0.50-1.80] comparing baseline with postnavigation follow-up rates).

Stage at Diagnosis

The sole efficacy study that focused on improving the number of patients diagnosed at an early stage of disease was a study of 487 women diagnosed with breast cancer at a public hospital in Atlanta. The results of this study showed an increase in the percentage of patients diagnosed with stage 0 disease from 12.4% when measured prior to the implementation of the patient navigation intervention to 25.8% when measured after implementation of the intervention (P < .005). Similarly, there was a reduction in the percentage of patients diagnosed with stage IV disease 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, and hence it is difficult to ascertain to what degree patient navigation contributed to the changes in stage at diagnosis.
Treatment Outcomes

Seven studies, including 2 RCTs,65,99 focused on the efficacy of patient navigation in improving cancer treatment outcomes65,66,87,89,94,98,99 and presented mixed results. In a large RCT, Ell et al found no statistical differences in treatment adherence rates for low-income, predominantly Latina women with breast and gynecologic cancer when 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.65 Skrutkowski et al discovered no significant differences in outcome measures for distress, fatigue, quality of life, and health care utilization for patients with lung and breast cancer in a population consisting of female, predominantly financially secure, Canadian patients (approximately one-half of whom were French speaking and one-half were English speaking) who received usual care and pivot nurse services (the Canadian pivot nurse position was described as being comparable to an American patient navigator).99

Five of these studies did not find any significant differences between patients who received patient navigation and those receiving usual care65,89,94,98,99 across a variety of outcome measures, including treatment adherence rates among a population of low-income, predominantly Latina women65; completion of radiation treatment (measured in days) among an underserved patient population98; distress, fatigue, quality of life, and health care utilization among a female, predominantly financially secure, Canadian patient population99; and changes in distress scores between hospital admission and discharge among a population of inpatients in the Midwest.89

Of the 2 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 patients with head and neck cancer among a predominantly male, Canadian patient population receiving patient navigation; findings regarding hospital utilization, however, were mixed.66 The second treatment efficacy study reported that navigated patients in a Native American patient population had an average of 3 fewer days of interruption in radiation therapy \( (P = .002) \).87 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 findings of the descriptive and qualitative studies (Table 2) provide particular insight into what patient navigators do or should do. Jean-Pierre et al qualitatively analyzed patient navigator interview data and categorized the tasks of patient navigation into 2 types of interventions: instrumental and relationship.95 Instrumental interventions are task-oriented or logistic in nature, such as helping a patient find transportation to appointments or information about their diagnosis. Relationship interventions, conversely, involve those efforts by the patient navigator that build and strengthen the interpersonal relationship between patient and provider.95

Davis et al identified 4 emergent themes from patient interview data that nicely broaden and expand on what patient navigators do or should do: (1) address access-to-care needs; (2) address emotional and practical concerns; (3) address patient family concerns; and (4) be involved throughout the continuum of care from diagnosis to survivorship.63

Understanding the barriers addressed by patient navigators 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 the different barriers patients face.79 The 3 most common barriers on which patient navigators spent their time were related to: (1) insurance and out-of-pocket expenses; (2) transportation issues; and (3) helping to manage the feelings and fears 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.79

Vargas et al conducted a case study designed to illuminate the initial patient navigation programs.90 They reported that the purpose of the first programs was to reduce cancer disparities in care related to race and poverty, and that this was accomplished by combining cultural sensitivity with aspects of disease management.90

Discussion

The past 3 years have produced a quantity of work in the cancer patient navigation literature comparable to that of the previous years combined. Using the same search methodology as the previous review by Wells et al,9 we 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 regarding 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. Although 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 improve 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 by Wells et al is an apparent increase in research concerning the processes that comprise 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 patient navigators “should” do from the perspective of the patient, in addition to studies reporting how patient navigators spend their time and on what specific tasks. Such process-oriented research may be beneficial in making broad improvements in patient navigation programs. However, given the great heterogeneity in patient navigation programs, the applicability of process-oriented research may not be universal.

In evaluating the results of the 2008 review and the present one, it is clear that the strongest evidence to date for the effectiveness of patient navigation is the improvements in cancer screening and outcomes related to the diagnosis of cancer; however, little progress has been made since the last review. Only one efficacy study 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); 2 descriptive studies also focused on diagnostic follow-up. Although there were several studies reviewed in the 2008 article that evaluated the effect of patient navigation on cancer diagnostic outcomes, many had methodological limitations. Taken together, the 2 reviews indicate that there is still a need to conduct high-quality research evaluating the effectiveness of patient navigation in improving cancer diagnostic outcomes such as a reduction in cancer diagnostic delays as well as in the number of patients lost to follow-up. There are only 2 known studies evaluating whether patient navigation was associated with a shift in the stage of cancer at diagnosis, but both studies combined patient navigation with other interventions that may have contributed to reductions in the diagnosis of 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 by Wells et al, evidence of the efficacy of patient navigation in improving these outcomes was inconclusive. This could be due to a number of issues related to study design or the fact that cancer patients may be able to obtain more resources and support during 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, which is the best known and most widely accepted method of evaluating an intervention effect. Two of the RCTs involved CRC screening (one of which was a pilot study and therefore is limited in terms of conclusive results), and 2 examined treatment in patients with breast, lung, and gynecologic cancers. Some studies lacked large sample sizes and some lacked comparison groups, which limit 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, 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 program, it is important to assess the needs of the populations served by that organization and tailor the intervention to those needs. Second, patient navigation is provided to underserved patients as well as to general patient populations. Third, 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 considering the implementation of a patient navigation intervention should focus the intervention on making improvements to a particular outcome of interest. Fourth, although individual patients may benefit from actions taken by patient navigators at various times across the cancer care continuum, currently the literature regarding the effectiveness of patient navigation is strongest for interventions that target cancer screening outcomes.

Despite the dramatic increase in the number of published studies concerning patient navigation and patient navigation programs in recent years, there is much we still do not know. Although individual patients may benefit from actions taken by patient navigators at various times across the cancer care 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. Furthermore, because the strongest results have been shown for cancer screening, there exists a need for more work regarding the impact of patient navigation on 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. 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 the results from the newest patient navigation research programs, the large government-sponsored studies, will provide much needed information in those 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 health care 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 and institutionalized widely with reimbursement mechanisms and training programs, and continually monitored and re-evaluated as necessary. Moreover, the purpose of patient navigation, namely to overcome both relationship and instrumental barriers to care, should be stressed. Thus, although patient navigation shows great promise in reducing cancer health disparities, much still needs to be done to assess and widely implement the best functioning programs to realize this goal.

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