Can Patient Navigation Improve Receipt of Recommended Breast Cancer Care? Evidence From the National Patient Navigation Research Program

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Published online ahead of print at www.jco.org on July 28, 2014.

Written on behalf of the Patient Navigation Research Program investigators.

Support information appears at the end of this article.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

Clinical trial information: NCT00613275, NCT00496678, NCT00375024, and NCT01569672.

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0732-183X/14/3225w-2758w/\$20.00

DOI: 10.1200/JCO.2013.53.6037

ABSTRACT

Purpose

Poor and underserved women face barriers in receiving timely and appropriate breast cancer care. Patient navigators help individuals overcome these barriers, but little is known about whether patient navigation improves quality of care. The purpose of this study is to examine whether navigated women with breast cancer are more likely to receive recommended standard breast cancer care.

Patients and Methods

Women with breast cancer who participated in the national Patient Navigation Research Program were examined to determine whether the care they received included the following: initiation of antiestrogen therapy in patients with hormone receptor–positive breast cancer; initiation of postlumpectomy radiation therapy; and initiation of chemotherapy in women younger than age 70 years with triple-negative tumors more than 1 cm. This is a secondary analysis of a multicenter quasi-experimental study funded by the National Cancer Institute to evaluate patient navigation. Multiple logistic regression was performed to compare differences in receipt of care between navigated and non-navigated participants.

Results

Among participants eligible for antiestrogen therapy, navigated participants ($n = 380$) had a statistically significant higher likelihood of receiving antiestrogen therapy compared with non-navigated controls ($n = 381$; odds ratio [OR], 1.73; $P = .004$) in a multivariable analysis. Among the participants eligible for radiation therapy after lumpectomy, navigated participants ($n = 255$) were no more likely to receive radiation (OR, 1.42; $P = .22$) than control participants ($n = 297$).

Conclusion

We demonstrate that navigated participants were more likely than non-navigated participants to receive antiestrogen therapy. Future studies are required to determine the full impact patient navigation may have on ensuring that vulnerable populations receive quality care.

J Clin Oncol 32:2758-2764. © 2014 by American Society of Clinical Oncology

INTRODUCTION

Over the last few decades, substantial advancement has been made in screening and treatment of breast cancer, resulting in reductions in breast cancer mortality.¹ However, not all women benefit equally from these advancements; low-income or black women continue to have higher breast cancer mortality rates compared with their higher income or white counterparts.²

The causes of these disparities have been attributed to a myriad of factors, including decreased screening rates,³ presentation at a more advanced stage,² increased prevalence of unfavorable basal-type cancer,⁴ and delays in treatment initiation or

incomplete treatment.^{5,6} Effective solutions for vulnerable patients are crucial⁷ as our national focus turns to improvement in access to and delivery of quality care.

Patient navigation programs have emerged as a potential solution to assist with cancer care delivery for underserved patients.⁸ Traditionally, patient navigation targeted the cancer screening process,⁸ but it has rapidly evolved within oncology practice so that navigators are expected members of oncology teams.⁹ Recent studies suggest a benefit of patient navigation within time to diagnosis and follow-up from an abnormal screening,¹⁰⁻¹⁹ but few studies have been performed to understand the impact of navigation after the diagnosis of breast cancer.^{13,20-22}

To our knowledge, this is the first national, multicenter study to evaluate whether patient navigation can improve quality of breast cancer care. Our hypothesis was that patients with breast cancer who are assigned a navigator are more likely to receive recommended standard treatment than patients without a navigator. To test this hypothesis, we performed a secondary analysis of the national Patient Navigation Research Program (PNRP) to study the effect of patient navigation on quality standards among women with newly diagnosed breast cancer.

PATIENTS AND METHODS

Study Sites and Data Sources

This study is based on data collected between 2006 and 2011 as part of the National Cancer Institute– and American Cancer Society–sponsored PNRP,²³ a coordinated effort among 10 research centers to implement and evaluate the timeliness and cost effectiveness of patient navigation for individuals ≥ 18 years old with abnormal screening tests or new cancer diagnoses for breast, cervical, colorectal, and/or prostate cancer. All participating centers implemented a patient navigation intervention²³ that focused on helping patients through their care in a timely fashion. The focus of joint national training was to support patients through their course of care and empower them to become knowledgeable about their own health. Navigators were provided basic education about breast cancer treatment but were specifically trained to not

provide treatment advice. All centers adopted the same inclusion and exclusion criteria, collected common data elements, and reported de-identified data to a data coordinating center, which assembled the national PNRP data set.

Participating centers included diverse community settings and thus conducted varied research designs to test the effectiveness of the intervention. Two centers used a clinical trial randomized at the individual level, two used a clinical trial randomized at the group (ie, delivery site) level, and five used a quasi-experimental design with nonrandom allocation of study sites into the intervention and control arms of the study.²⁴ Although study centers also varied in their implementation of navigators in relation to the oncology teams, navigators had no contact with control patients at any of the study centers. Examples of the relationship of the navigation teams to the oncology treatment teams include navigators based in the primary care setting or navigators working on the same floor as the oncology team but in a different office space. Furthermore, there were no differences in clinical services available across intervention and control sites for each respective center. Detailed information on individual center settings is published elsewhere.^{10-12,14,16,18,19,25}

Because our purpose was to evaluate the quality of cancer care among women with confirmed breast cancer, we used a subset of data collected from patients with breast cancer ($n = 1,288$) reported by eight centers. Participants were recruited for the study after receipt of an abnormal cancer screening test, detection of a breast abnormality, or diagnosis of breast cancer. Our sample included women navigated through the process of diagnosis ($n = 6,755$) who developed breast cancer ($n = 662$) or who entered the study with a breast cancer diagnosis ($n = 626$; Fig 1). If participants were assigned to receive navigation and had a diagnosis of breast cancer, navigation was provided

Fig 1. CONSORT diagram. Chemo, chemotherapy; Ctrl, control group; ER, estrogen receptor; LN, lymph node; Nav, navigated group; PR, progesterone receptor; Rad, radiation; T, tumor.

through the end of cancer treatment, which included surgery, chemotherapy, and radiation. Exclusion criteria included a previous recent history of cancer, previous patient navigation support, pregnancy, initiation of cancer treatment before consent was given for the study, and cognitive conditions that would exclude participation. Clinical data, including those assessing whether quality care standards were met, were abstracted from the medical records of eligible participants. Demographic characteristics were collected from administered questionnaires, primary care medical records, or hospital registration data at the time of enrollment onto the study.²³

Institutional review board approval was obtained at each intervention center included in our analysis. Breast cancer intervention centers included centers in Boston, Chicago, Denver, Ohio, Rochester, San Antonio, Tampa, and Washington, DC. Each center served low-income, uninsured, or publicly insured members of racial/ethnic minority groups at local community health centers or ambulatory care sites both within and outside safety net hospitals.

Measures

Quality of care. The American Society of Clinical Oncology/National Comprehensive Cancer Network guidelines provide recommendations for standard cancer treatment.²⁶ We used three breast cancer standards as our quality care metrics (Table 1). They were as follows: initiation of antiestrogen therapy in patients with hormone receptor–positive breast cancer; initiation of postlumpectomy radiation therapy (excluding women > 70 years old with tumors < 2 cm, negative lymph nodes, and positive hormone receptors); and initiation of chemotherapy in women less than 70 years old with triple-negative tumors more than 1 cm. Our main outcomes were receipt of quality care (yes or no) for each of the metrics.

Demographic characteristics. Age was treated as a continuous variable. Race/ethnicity was categorized as black (reference), Hispanic, non-Hispanic white, or other/missing. We collapsed responses to language spoken at home into a dichotomous variable (non-English [reference] *v* English). Insurance status was categorized as uninsured (reference), public insurance, or private insurance.

Statistical Analysis

We compared the demographic characteristics of the participants with breast cancer stratified by navigated (intervention) versus control (usual care) participants using *t* tests for continuous variables and χ^2 tests for categorical variables. Fisher's exact test was used when expected frequencies were less than 5 for at least 80% of the frequencies. Because the outcomes of interest are dichotomous, we used logistic regression models. The primary regressor of interest was study type (navigated *v* control participant). Multivariable logistic regression models were used to test whether navigated participants were more likely to receive quality care than control participants. Insufficient variation in the chemotherapy outcomes as a result of the small number of eligible participants in the sample prevented us from performing the multivariable analysis for this metric. For example, at five of the nine study sites, 100% of the navigated patients received recommended therapy, and at four of the nine study sites, 100% of the control patients received recommended therapy. The general association between the intervention and chemotherapy treatment was assessed, with an adjustment for site, by the Cochran-Mantel-Haenszel test. Because the Cochran-Mantel-Haenszel estimate of the odds ratio (OR) is based on only four of the eight sites, we also report the proportion of navigated and control patients who received recommended chemotherapy treatment for all eight sites.

Models were adjusted using a predefined standard set of covariates that included age, race/ethnicity, insurance status, and language spoken at home. To control for all measured and unmeasured site-level characteristics,²⁴ we included a set of indicator variables (eg, Boston, Chicago) for site in our regression models. Thus, our results are adjusted for all pre-existing between-site differences. By doing so, we have estimated a fixed effects model that limits the range of generalization to these specific sites (ie, we have not treated them as a sample of sites via a random effects model).

We calculated ORs and associated 95% CIs for the independent variables, which reflect the odds that a navigated participant received recommended care relative to the odds that a control participant received recommended care, controlling for all other factors. *P* values were two-sided throughout, and statistical significance was set at *P* = .05. Because this was a secondary data analysis of a previously collected sample of participants, statistical power was not calculated prospectively. All statistical analyses were performed using Stata version 11 (StataCorp, College Station, TX).

RESULTS

Table 2 lists participant characteristics by intervention status (navigated *v* control) for each quality metric outcome and as a whole. There were 761 participants eligible for antiestrogen therapy, 552 eligible for radiation therapy, and 158 eligible for chemotherapy. The outcome groups are not mutually exclusive. There are 1,004 women in the data set, with a mean age of 56.2 years (standard deviation, 11.4 years). Overall, the participants were racially and ethnically diverse, with a majority being nonwhite (black, 37.5%; Hispanic, 22.3%; other, 3.9%) and 36.3% being white. Most patients were English speakers (79%). Although many patients had private insurance (48.6%), slightly over half had public insurance (38.0%) or no insurance (13.4%). Of the 1,004 women in the data set, 359 (35.8%) were recruited at sites with individual randomized controlled trial designs, 38 (6.8%) were recruited at sites with group randomized designs, and 577 (57.5%) were recruited at sites with quasi-experimental designs.

Across the quality metric cohorts, there were similar sociodemographic patterns when comparing navigated and control participants. Although there were differences in sociodemographics between the navigated and control participants, similar trends existed across all cohorts. For example, navigated and control participants were similar in age for all three metric cohorts. In addition, navigated participants were consistently less likely to be white or have private insurance. Among the antiestrogen therapy group, navigated participants were more likely to be non-English speakers.

Table 3 lists findings from the logistic regression model for the antiestrogen therapy treatment cohort and the postlumpectomy radiation cohort. When controlling for age, race/ethnicity, language, insurance, and site, navigated participants who were eligible for antiestrogen therapy were more likely than non-navigated control

Table 1. Definition of Quality Care by Treatment Type

Treatment Type	No. of Patients	Eligibility Criteria	Quality Care
Antiestrogen therapy	761	ER or PR positive	Receipt of antiestrogen therapy
Radiation therapy	552	Receipt of breast-conserving surgery (excluded patients age > 70 years, node negative, with tumors < 2 cm, and hormone receptor positive)	Receipt of radiation therapy
Chemotherapy	158	Triple negative (ER, PR, HER2 negative), tumors > 1 cm, and age < 70 years	Receipt of chemotherapy

Abbreviations: ER, estrogen receptor; HER2, human epidermal growth factor receptor 2; PR, progesterone receptor.

Table 2. Sociodemographic Characteristics of Patients With Newly Diagnosed Breast Cancer in the Patient Navigation Research Program by Intervention Status

Characteristic	Hormone Therapy (n = 761)			Radiation Therapy (n = 552)			Chemotherapy (n = 158)			Total (N = 1,004; Nav, n = 498; Ctrl, n = 506)
	Nav (n = 380)	Ctrl (n = 381)	P	Nav (n = 255)	Ctrl (n = 297)	P	Nav (n = 86)	Ctrl (n = 72)	P	
Age, years			.602			.962			.918	
Mean	57.1	56.7		56.8	56.8		51.4	51.2		56.2
SD	11.4	11.6		11.4	10.5		9.7	10.5		11.4
Race, %			< .001			.006			.798	
Black	32.6	35.4		39.2	42.1		46.5	43.1		37.5
Hispanic	32.4	14.2		25.1	14.1		22.1	18.1		22.3
White	32.1	45.4		33.3	38.7		27.9	34.7		36.3
Other	2.9	5.0		2.4	5.1		3.5	4.2		3.9
Language, %			.224			.027			.292	
Non-English	20.8	14.0		16.9	24.6		14.0	20.8		20.9
English	79.2	86.1		83.2	75.4		86.1	79.2		79.1
Insurance status, %			.001			.060			.009	
None/uninsured	17.2	8.7		13.1	10.1		25.0	6.9		13.4
Public	39.8	38.1		39.1	32.0		34.5	40.3		38.0
Private	43.0	53.3		47.8	57.9		40.5	52.8		48.6
Site, %			< .001			< .001			.013	
A	4.0	7.6		5.2	7.7		1.2	0		5.0
B/C	6.6	8.9		4.4	8.3		8.1	8.3		7.5
D	10.3	9.5		9.6	8.3		9.3	9.7		9.8
E	5.0	2.6		5.5	2.2		1.2	1.4		3.3
F	6.6	22.4		19.1	6.7		30.2	9.7		14.8
G	3.4	3.4		2.2	2.6		2.3	2.8		3.5
H	34.9	21.1		23.2	45.2		18.6	40.3		30.3
I	26.5	27.4		30.9	18.9		29.1	27.8		26.0

Abbreviations: Ctrl, control; Nav, navigated; SD, standard deviation.

participants to receive antiestrogen therapy (OR, 1.73; 95% CI, 1.19 to 2.53; $P = .004$). Navigated participants who were eligible for radiation therapy were no more likely than controls to receive radiation (OR, 1.42; 95% CI, 0.80 to 2.54; $P = .22$).

For the chemotherapy-eligible cohort, because of the small sample size and little variation in the receipt of quality care between control and navigated participants, we report the percentage of women who received recommended quality care (Table 4) within the control and navigated arms. Of the eight sites, three sites had 100% of both the control and navigated participants receive the recommended chemotherapy treatment. One site lacked any eligible control participants, with only one eligible navigated participant receiving chemotherapy. Another site had similar rates of receipt of chemotherapy in both the navigated and control groups. There were sizeable differences at the remaining three sites, with higher proportions of women in the control arms receiving recommended treatment at two sites. In the Cochran-Mantel-Haenszel test, there is evidence of a negative relationship between the intervention and receipt of recommended chemotherapy treatment, after stratifying by site, in the four sites where an association can be estimated (OR, 0.36; 95% CI, 0.16 to 0.80; $P = .0092$).

DISCUSSION

Current literature documents that racially diverse women of low socioeconomic backgrounds are more likely to have delays in treatment,²⁷ have a poor understanding of prognosis,²⁸ and be subject to

processes of care that result in suboptimal use of treatment.^{29,30} The promise of patient navigation to address these issues has led to its rapid adoption into both primary care and cancer clinics nationwide, despite a lack of studies demonstrating benefit³¹ and many proposed methods of testing efficacy.³²⁻³⁵ To our knowledge, our study is the first national multisite group study to demonstrate that navigated participants eligible for antiestrogen treatment are more likely to initiate recommended therapy than controls. These results suggest that patient navigation can be a promising solution/intervention, particularly because the current literature suggests that minority women of low socioeconomic status are at risk of low adherence to antiestrogen therapy.^{35a}

Few published studies evaluate the relationship between patient navigation and quality of breast cancer care.^{13,20-22} Most existing literature in patient navigation focuses on screening and diagnosis, with few articles that primarily study the effect of navigation after the diagnosis of cancer. To our knowledge, four published studies focus on navigation and breast cancer care, but each uses distinct methods and outcome metrics, and all are limited by small samples and retrospective analysis. Two single-institution studies^{21,22} found that patient navigation improved quality of care, whereas another study¹³ demonstrated that both navigation and control groups had high adherence rates. Finally, a retrospective study²⁰ found that navigated patients had concordance rates similar to elite National Comprehensive Cancer Network institutions for antiestrogen therapy, radiation therapy, and chemotherapy.

Table 3. Results of Multivariable Logistic Regression Model: OR of Receiving Quality Measures Comparing Navigated With Non-Navigated Patients

Variable	Hormone Therapy			Radiation After Lumpectomy		
	OR	95% CI	P	OR	95% CI	P
Group						
Control	Ref			Ref		
Navigation	1.73	1.19 to 2.53	.004	1.42	0.80 to 2.54	.22
Site						
A	Ref			Ref		
B/C	0.20	0.07 to 0.54	.002	0.47	0.01 to 2.23	.34
D	0.60	0.20 to 1.77	.35	1.17	0.23 to 5.88	.85
E	1.26	0.28 to 5.78	.76	0.16	0.03 to 0.83	.03
F	0.77	0.26 to 2.26	.64	0.49	0.12 to 2.04	.33
G*	—	—	—	0.29	0.05 to 1.74	.18
H	0.18	0.07 to 0.46	.00	0.32	0.09 to 1.20	.09
I	0.79	0.29 to 2.12	.64	1.10	0.26 to 4.73	.90
Race						
Black	Ref			Ref		
Hispanic	1.06	0.52 to 2.15	.88	0.49	0.19 to 1.26	.14
White	0.65	0.40 to 1.04	.07	0.79	0.41 to 1.53	.49
Other	0.40	0.16 to 0.98	.05	0.42	0.12 to 1.53	.19
Language						
Non-English	Ref			Ref		
English	1.37	0.84 to 2.26	.21	0.84	0.43 to 1.66	.62
Insurance						
Uninsured	Ref			Ref		
Public	1.53	0.80 to 2.95	.20	0.95	0.37 to 2.41	.91
Private	1.54	0.78 to 3.01	.21	1.45	0.54 to 3.86	.46

NOTE. Age is treated as a continuous variable.

Abbreviations: OR, odds ratio; Ref, reference.

*Site G cannot be included in the model because the key variable, study group, perfectly predicts failure in the outcome (ie, all four control participants did not receive National Comprehensive Cancer Network–recommended care).

Each of these studies evaluated patient navigation with different quality metrics, underscoring the ongoing difficulty in how to define best practices in patient navigation. Guadagnolo et al³⁴ proposed specific core metrics to evaluate patient navigation during cancer care, including goals of treatment, timeliness of care, treatment adherence, and patient satisfaction, among others. These metrics can be used as a

guideline for future targeted studies to consistently document the ongoing benefits of patient navigation during cancer diagnosis and treatment.

Our approach in understanding the impact of patient navigation on cancer care focused on clinical treatment outcomes. We were unable to investigate quality metrics such as receipt of recommended care or delays to completion of treatment because our data set was limited with respect to variables that could adequately answer those questions. Fortunately, we were able to extract clinical data linked to guideline adherence, based on the following three separate quality metrics of breast cancer care: initiation of antiestrogen therapy, radiation therapy, and chemotherapy. These treatment recommendations are well studied and universally accepted to have a direct benefit of health outcomes and yet are least likely to be received by the population targeted by the national PNRP.³⁶

Although we are able to report a positive association between navigation and receipt of antiestrogen therapy, our study cannot elucidate the process or mechanism behind how patient navigation may be effective. Questions remain regarding the specific tasks or barriers addressed that may have helped to facilitate treatment. Furthermore, the navigator tasks could vary by the type of therapy (ie, antiestrogen treatment, radiation treatment, or chemotherapy) and specific navigator interaction (ie, financial assistance, transportation, or patient education). Perhaps patient navigators may have helped with obtaining prescriptions or increasing patient understanding of the benefits of antiestrogen treatment.

Barriers addressed in radiation therapy may require a different set of actions compared with assistance in obtaining antiestrogen therapy. For example, assistance with transportation or managing work schedules could have played a more prominent role. Navigation nationwide is variable,³⁷ and how one navigator may help improve the quality of care is highly dependent on his or her specific actions or interactions.

Because of small sample size and limited variation in the receipt of recommended chemotherapy treatment, we could not fit our full logistic regression model to assess the relationship between patient navigation and chemotherapy. Results from the Cochran-Mantel-Haenszel test, which are based on only four sites, suggest a negative association between patient navigation and receipt of chemotherapy, but these results should be compared alongside the descriptive results that we report for all eight sites. These results reveal that sites with small samples show a preponderance of patients receiving chemotherapy, but at sites with large samples, we observe that between 20% and 33% are not receiving chemotherapy, and the value of the addition of a navigator is inconclusive from the data we have. These limited findings suggest that further targeted study of the likelihood of receiving clinically recommended chemotherapy care in a large sample of patients is warranted.

Limitations of our study include that these findings are a secondary analysis; the data set was not designed to answer our question. These results must be interpreted as exploratory and hypothesis generating. Furthermore, the PNRP study was quasi-experimental in design at five of the nine sites, without the traditional safe guards within a uniformly randomized controlled trial. Notably, there are distinctive characteristics that differ between our navigated and control groups. The navigated group has a higher percentage of racially diverse patients and non-English speakers and is also less likely to be privately insured. These differences may in fact suggest that our results are more meaningful. We are also limited by the amount of missing

Table 4. Patients Who Received Chemotherapy by Research Site and Assignment to Navigation or Control Group

Site	Total No. of Patients	Navigated Patients Who Received Chemotherapy		Control Patients Who Received Chemotherapy	
		No. of Patients	%	No. of Patients	%
A	1	1	100	0	0
B/C	13	7	100	6	100
D	15	8	100	5	71
E	2	1	100	1	100
F	33	15	58	7	100
G	4	2	100	2	100
H	45	8	50	28	97
I	45	17	68	14	70
Total	158	59	69	63	88

data within our data set, which further underscores the fact that these results are a secondary analysis that can only serve to guide future work. In an effort to address this issue, we were able to retrieve some but not all missing data. These missing data may reflect patients who went elsewhere for their care and thus could have had fewer or more delays in care. Another limitation is our inability to evaluate adherence or completion of treatment, because we were only able to identify initiation of treatment. Finally, to achieve sufficient sample sizes, we combined data that originated from sites implementing different research designs to test their navigator programs. We considered and rejected pooling data by research design because of a belief that the sites varied across multiple dimensions and focusing on research design would ignore other site differences. Instead, our model uses fixed effects to adjust for site differences.

Overall, to our knowledge, this is the first national study to demonstrate that patient navigation may have a positive effect on the initiation of antiestrogen therapy in vulnerable populations. Our lack of a consistent finding in favor of navigation for all three quality treatment metrics suggests that the benefits of navigation may depend on the type of barriers addressed (eg, financial, transportation) and personal interaction (education and/or understanding regarding illness, treatment, and so on). More research is needed to confirm these findings, identify the mechanism or process by which navigation improves receipt of recommended treatment, and define the patient populations and settings where patient navigation has the maximal benefit. Targeting resources to the right area (eg, timeliness, transportation, or logistical help) will identify which aspects of care are best suited for patient navigation to make a difference.³⁸

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: None **Consultant or Advisory Role:** None **Stock Ownership:** None **Honoraria:** Steven R. Patierno, Pfizer **Research Funding:** None **Expert Testimony:** None **Patents, Royalties, and Licenses:** None **Other Remuneration:** None

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Manuscript writing: All authors

Final approval of manuscript: All authors

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Support

Supported by National Institutes of Health Grants No. U01CA116892, U01CA117281, U01CA116903, 01CA116937, U01CA116924, U01CA116885, U01CA116875, U01CA116925, and R25CA090314; American Cancer Society Grants No. SIRSG-05-253-01 and CRP-12-219-01-CPPB; the Avon Foundation; and the Boston Medical Center Carter Disparities Fund.

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Acknowledgment

Presented in part at the American Society of Clinical Oncology Quality Care Symposium, November 30-December 1, 2012, San Diego, CA; and the 2012 Annual Meeting of the Massachusetts Society of Clinical Oncologists, November 8, 2012, Dedham, MA.

Appendix

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The following members of the Patient Navigation Research Program contributed to this study.

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