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The Breast Cancer Quality of Care Study (B-QUAL): A multi-center study to determine causes for non-compliance with breast cancer adjuvant therapy

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Abstract

In oncology, quality of care is a major issue for patients and providers. Significant variations in care, including non-receipt of adjuvant systemic therapy, non-adherence to therapy, and/or early discontinuation of therapy, occur frequently and may impact survival. Reasons for these variations are not well understood, but may play a role in the prominent disparity in breast cancer survival between blacks and whites. Since May 2006, the Breast Cancer Quality of Care Study (B-QUAL) has recruited 1158 women with non-metastatic breast cancer from several centers across the country, with completed data on 1057 participants to date. Detailed information on demographic, behavioral, biomedical, and emotional factors related to chemotherapy use was collected on each participant at baseline and at two follow-up interviews during the first 6 months. In addition, for women with ER+ tumors, further questionnaires were completed every 6 months regarding hormonal therapy use. Each participant was also asked to provide a DNA sample, and to allow medical record review. We surveyed physicians providing care to the study participants regarding attitudes toward adjuvant treatment. The mean age of participants was 58 years (SD 11.6), and

15% (n=160) were black. The majority had an annual household income <\$90,000 (n=683), had college education or higher (n=802), 55.9% were married, and 57.9% were not currently employed. Seventy-six percent had hormone-receptor-positive tumors, 49.9% initiated chemotherapy and 82.7% started hormonal therapy. Blacks differed significantly from women of other races with regard to income ($p < .0001$), education ($p = 0.0005$), hormone receptor status ($p = 0.02$), and tumor grade ($p = 0.0002$). The main endpoints of the study are non-initiation of chemotherapy or hormonal therapy, non-adherence to therapy and early discontinuation of therapy. Treatment and outcomes will be compared on the 15% of participants who are black versus other participants. The B-QUAL Study will be a rich ongoing source of information regarding reasons for differences in receipt of both adjuvant chemotherapy and hormonal therapy. This information may be useful in planning interventions to improve quality of care.

Keywords

Quality of care; adjuvant therapy; adherence; breast cancer; persistence; early discontinuation; racial disparities

Introduction

Among the most important advances in oncology has been the use of adjuvant therapy (radiation, hormonal therapy, and chemotherapy) for breast cancer (1–2). Despite this, studies indicate that substantial variations occur in the use of these modalities of therapy (3–5). Some patients never initiate these potentially life-saving therapies (6), while others have significant delays in initiation (7–9), and some discontinue therapy early (3, 10). Significant deviation from recommended treatment may lead to reductions in survival benefit (3, 7–8). The prevalence and causes of deviations from treatment guidelines in the community and their impact on survival have not been well studied. Furthermore, there are likely to be higher risk subgroups that are particularly vulnerable to deviations from standard guidelines in cancer care. Thus, an improved understanding of factors that predispose to non-compliance with recommended treatment would provide targets for future interventions to improve breast cancer survival.

Disparities exist in survival outcomes between black and white women with breast cancer (11); variations in initiation and compliance with treatment could play a role in these differential outcomes. For instance, recent studies have suggested that black women are less likely to receive optimal systemic adjuvant therapy than white women (12). Blacks were more likely to have delays in the initiation of both adjuvant chemotherapy and radiotherapy and these delays were associated with worse survival (7–8). Our studies and those of others have also found that 30–50% of women discontinue breast cancer adjuvant chemotherapy early and that this significantly impacts survival outcomes (3, 13), with blacks more likely to discontinue early (14–15).

Medication compliance has been a major issue in medicine for decades (16–18). Patients frequently do not take their medications as prescribed (non-adherence) or discontinue therapy early. This is a major cause of treatment failure and poorer survival outcomes (16). Non-adherence to oral antineoplastic agents, such as hormonal agents for breast cancer (5, 19–23), imatinib for chronic myelogenous leukemia, or capecitabine for breast cancer (24–25), is even more common than non-adherence to infusional chemotherapeutic agents despite evidence that these therapies improve survival. In fact, the issue of non-compliance has proven to be as large a problem in oncology as for other branches of medicine (14–15, 26). This occurs despite the beneficial impact that this therapy is likely to have on cancer mortality.

A number of studies have explored reasons for non-compliance with these treatments (19–23, 27–28); however, these studies have generally been limited in size or restricted to specific subgroups, such as the elderly. One understudied reason for non-compliance could be toxicities experienced with chemotherapy or hormonal therapy. There is wide variability in distributions of adverse events among women receiving similar treatment regimens, and part of this variability could be due to inherent genetic differences in metabolism of the drugs, or response to their cytotoxic effects. This inter-individual variability in drug effects, termed pharmacogenomics, could result in some women less willing to comply with or complete therapy regimens. Psychosocial factors may also contribute to non-compliance with antineoplastic therapies with potential differential effects in blacks (14).

In the Breast Cancer Quality of Care Study (B-QUAL), we are conducting a prospective cohort study among women with non-metastatic breast cancer treated at several sites across the United States. Our purpose is to investigate in a comprehensive fashion the causes for non-initiation, non-adherence (taking <80% of the prescribed medication), and early discontinuation of adjuvant chemotherapy and hormonal therapy. We take a multidimensional approach to this investigation by including patient, tumor, physician, and pharmacogenomic characteristics in our study design. In addition, we tried to recruit sufficient black participants to enable us to compare patients by race with respect to factors which may help explain black-white differences in breast cancer mortality.

Materials and methods

Overall study design

The Breast Cancer Quality of Care Study (B-QUAL) is a prospective cohort study of patients recruited at or through Columbia University Medical Center (CUMC) in New York, Kaiser-Permanente of Northern California (KPNC), Henry Ford Health System (HFHS) in Detroit, MI, and Mount Sinai School of Medicine (MSSM) in New York.

Women newly diagnosed with non-metastatic breast cancer were recruited at each site as soon as possible following diagnosis and were ineligible after three cycles of adjuvant chemotherapy. Figure 1 outlines the study design. At CUMC and HFHS, patients were recruited directly into this study. At KPNC and MSSM, recruitment was piggybacked onto existing studies. The Pathways Study at KPNC is an ongoing study of breast cancer survivorship with a similar recruitment plan (29). The study at MSSM was a case-control study of behavioral and molecular epidemiologic risk factors for breast cancer (30). Participants enrolled in each study were introduced to and invited to participate in our study. For all consenting participants, a questionnaire was conducted at enrollment following informed consent. Women also completed follow-up questionnaires at 2 and 4 months (roughly corresponding to mid-chemotherapy and completion of chemotherapy). For participants whose tumor was hormone receptor-positive, a questionnaire regarding hormonal therapy is administered every 6 months for the first 2 years following study entry and annually thereafter (this is ongoing). A blood or saliva specimen for DNA extraction was obtained at baseline. Six to 18 months post-treatment, the medical chart was audited to collect information related to the tumor, treatment, and adverse events using the Common Toxicity Classification of Adverse Events (CTCAE). Physicians whose patients had named them as care providers were asked to complete a questionnaire about their attitudes towards decision-making with regard to treatment.

The study was approved by the Institutional Review Boards of each recruitment site and the U.S. Army Medical Research and Materiel Command Office of Research Protections and Human Research Protection Office. Written informed consent and HIPAA authorization

were obtained from patients prior to initiation of study procedures. A waiver of informed consent was granted for the physician survey study.

Study sites

Kaiser-Permanente of Northern California (KPNC)—KPNC is the country's largest and oldest group model pre-paid, integrated health plan, providing health care and medications to approximately 3.2 million members through 3,300 physicians, 32 outpatient clinics, and 18 hospitals in California. Largely concentrated in urban areas around the San Francisco Bay Area, KPNC also has a presence in the Central Valley. Although most members enroll through their employment, many are members through MediCal (a low-income insurance). Members are very similar to the general population for ethnicity, education, employment status, marital status, screening practices, and prevalence of medical conditions, when compared with population-based data.

Henry Ford Health Care System (HFHS)—The Henry Ford Health System, one of the nation's leading vertically integrated health care systems, is organized in four regions encompassing Metropolitan Detroit in Wayne County, Michigan. Founded in 1915 by the auto pioneer, Henry Ford, HFHS is a comprehensive health system comprised of 6 hospitals, 27 medical centers, and 7 specialized facilities that provide health insurance, and acute, specialty, primary and preventive health care services to approximately 800,000 southeast Michigan residents, 40.5% of whom are black. Services provided by HFHS in 2010 included over 3.2 million outpatient visits, 99,700 hospital admissions, and 88,000 surgeries. In 2000, median household income by zip ranged from over \$152,000 to a low of \$9,347. Over 450,000 people in HFHS are non-HMO participants, representing diverse payer groups including Blue Cross, other commercial, Medicare, Medicaid, and private pay.

New York City Recruitment Sites—Participants in NYC were recruited directly from Columbia University Medical Center (CUMC) and from among patients enrolled in a study conducted by collaborators at the Mount Sinai School of Medicine (MSSM). CUMC is located on a 20 acre site in the Washington Heights section of Manhattan in New York City. Formerly known as Columbia Presbyterian Medical Center, CUMC is comprised of the 5 acute-care and community hospitals, 19 acute care facilities, 10 continuum of care facilities, home-health agencies, ambulatory sites and specialty institutes, as well as the Physicians and Surgeons Medical School, School of Public Health and School of Nursing. With more than 17,000 employees, CUMC provided 1.4 million outpatient visits and 71,000 ambulatory surgeries to the residents of Manhattan, Brooklyn, Queens, and the Bronx as well as Westchester, Long Island, New Jersey, Connecticut, and several upstate New York counties in 2010. Around 12% of breast cancer patients seen are black.

Through their DOD Center for Interdisciplinary Biobehavioral Breast Cancer Research case-control study for breast cancer in black and white women in New York City (Women's Circle of Health Study (WCHS) (30), MSSM created a citywide network of recruitment sites of hospitals with large referral patterns for black breast cancer patients. These sites included Mount Sinai Medical Center, Mount Sinai Queens Hospital Center, Kings County Hospital, New York Hospital Queens, Montefiore Medical Center, Jacobi Medical Center, Beth Israel Medical Center and St. Luke's/Roosevelt Hospital, encompassing all 5 boroughs of New York City. Due to the way recruitment was conducted for the underlying case/control study, it was difficult to recruit to our study and, as a result, recruitment was terminated early.

Subject eligibility

Starting May 2006, we recruited women who were >20 years of age and newly diagnosed with primary, histologically confirmed invasive breast cancer (stages 1–3). Women were

consented prior to administration of the third cycle of chemotherapy (if they received chemotherapy) or within 3 months of diagnosis. Women who were non-English speaking, had a prior history of cancer, except for non-melanoma skin cancer, had a documented or self-reported history of significant memory deficit, and who did not have a telephone were excluded. Patients with ductal carcinoma *in situ* (DCIS) or stage 4 cancer at diagnosis were also excluded. Refusal of blood or saliva samples was not an exclusion from entry into the study.

Subject recruitment

At KPNC, after passive physician consent, an invitation letter for the Pathways Study was sent to each potential subject with an opt-out postcard. If the postcard was not returned within 2 weeks, a telephone call was placed to the woman to determine her interest and eligibility for the Pathways Study. Interested eligible women were interviewed face-to-face for the Pathways Study. At this time, women were given information related to the B-QUAL study and if interested, a separate informed consent for the B-QUAL Study was obtained. They then responded to the baseline Pathways interview questionnaire and were asked to provide biological specimens. The KPNC interviewer then gave the name and contact information of the woman and a copy of the informed consent to the Columbia research team.

At HFHS, a recruiter was present at weekly breast cancer tumor board meetings and the multidisciplinary breast care clinic where many newly diagnosed breast cancer cases are presented. The HFHS staff obtained the physician's consent to approach potentially eligible patients, confirmed eligibility, and then contacted them by telephone to determine interest in participating. If interested, the consent form was sent by mail to the women. After receipt of signed consent, the staff provided the patient's information to the Columbia interview team.

At CUMC, an onsite member of the Research Recruitment Minority Outreach core of the Herbert Irving Comprehensive Cancer Center reviewed appointment lists of newly diagnosed breast cancer patients for eligibility. For potential subjects, physician consent was obtained and then the patient was approached in person for informed consent during a visit. Contact information for consented women was forwarded to the Columbia interview team.

At MSSM sites, recruitment to WCHS was through physician referral. Subjects were identified initially by surgeons and oncologists at collaborating hospitals. Physicians signed patient referral forms and passed these to MSSM recruiters indicating that the subject could be contacted by telephone. Appointments were set to meet with patients to obtain informed consent to participate in the WCHS, during which women were invited to participate in the B-QUAL study. If interested, the MSSM recruiter obtained informed consent for our study and shared the names and contact information with the CUMC interview team.

Upon receipt of names and contact information of consented women from each of the recruitment sites, Columbia interviewers contacted women by telephone, confirmed eligibility, and conducted the baseline and subsequent interviews over the telephone.

Study population

Information on study accruals and survey completion is shown in Figure 2. In total, 1512 women were approached to participate in B-QUAL. Of these, 1293 (85.5%) women were eligible for our study and 1158 (89.6%) consented and completed the initial baseline interview. Among those who completed the baseline interview, 1128 (97.4%) completed the first follow-up questionnaire and 1071 (92.5%) completed the second follow-up questionnaire.

There were 788 women with hormone receptor-positive breast cancer in the sample. Of these, 710 (90.1%) have completed the initial hormonal therapy questionnaire at 6 months. To date, we had 590 hormonal therapy follow-up questionnaires completed at 12 months, 483 at 18 months, 257 at 24 months, and 65 at 36 months, with follow-up ongoing (see Figure 2).

The medical charts of 1057 subjects have been audited thus far. Blood or saliva specimens for DNA analysis were obtained from 1075 (92.8%) of the 1158 women who completed the baseline questionnaire.

Study procedures

Patient interviews—At least a week before the telephone interview, the study team mailed each participant a letter stating the date of the upcoming interview and a sheet displaying response options to the questions that would be asked during the telephone interview. Reminder calls were also placed to participants on the day before the interview. On completion of the baseline, second follow-up, and second and fourth hormonal therapy interviews, subjects were mailed a gift card valued at \$20.

Baseline interviews were conducted after definitive diagnosis and prior to administration of the third cycle of chemotherapy, if chemotherapy was to be administered. For those not receiving chemotherapy, the baseline interview was conducted within 12 weeks of diagnosis. This interview was approximately 60 minutes in duration.

Follow-up interviews were conducted at 4–6 and 12–24 weeks, respectively, after completion of the baseline interview. Each telephone interview lasted 30–45 minutes. For those who reported during any of the first 3 interviews that they were either ER/PR positive or that their physician recommended hormonal therapy as treatment, additional surveys related to hormonal treatment were conducted every 6 months for the first 2 years of enrollment and annually thereafter until conclusion of the study. These interviews were approximately 15 minutes long.

Table 1 displays the study measures used to evaluate quality of care. They represented 4 domains: medical experiences, cognitive factors, emotional factors, and social relations factors. Medical experience measures included questions about patient-physician communication, symptom experience, treatment satisfaction, and quality of life. In the cognitive domain, we queried subjects regarding medical literacy, pre-treatment expectations, treatment decision-making, general medical mistrust, and fatalism. We assessed emotional factors, using questions about benefit finding, spirituality, religiosity, optimism, and emotion regulation. As measures of social relations, we collected information surrounding social support, quality of medical care, stress, and attachment styles.

Medical record review—Approximately 6–18 months after each patient is diagnosed, the team obtains her medical record information from the appropriate record system. Record review is ongoing. Abstractors collect information on tumor characteristics (size, stage, grade, histology, number of positive nodes, ER/PR status, HER2 over-expression, and, when available, OncotypeDx score). Information is also abstracted on initiation and use of chemotherapy, such as prescribed chemotherapeutic agents, drug regimen schedule, planned number of treatment cycles, number of completed cycles, use of biologics and bisphosphonates, number, frequency and severity of adverse events using Common Toxicity Classification of Adverse Events (CTCAE), reasons for treatment non-initiation, dose delays and early discontinuation. Also, the use of supportive medications (granulocyte stimulating factor, erythropoietin, antiemetics, etc.) and complete blood counts for each chemotherapy cycle are recorded. For hormonal therapy, medical chart audit is performed to determine

whether this treatment was recommended and initiated as well as the agent recommended, if the participant switched agents and reasons for switching, adverse events, how long treatment was taken, and reasons for early discontinuation.

For KPNC patients, three chemotherapy administration electronic databases have provided data: the Case Management for Medical Oncology with Laboratory and Outcome Tracking (CAMMOLOT), the Cancer Oncology Pharmacy System (COPS) and the Beacon system. Also, data from the KPNC Cancer Registry were abstracted to obtain information on tumor characteristics and patient treatment. Patient demographics and other information were obtained from the general medical record systems of KPNC. Information on use of hormonal therapy was obtained from the Pharmacy Information System.

For HFHS patients, data were obtained from the HFHS administrative database, known as the Corporate Data Store, and from the HFHS electronic medical record system known as Care+. Tumor characteristics are obtained from the HFHS Tumor Registry.

For patients recruited at CUMC, a data abstractor reviews the medical records of each subject in the study manually to obtain and confirm information recorded with regard to tumor characteristics, treatment, and adverse events. Abstractors also manually abstract data from the records of subjects recruited at hospitals in the MSSM sites throughout New York City. For women who sought treatment at a hospital or center outside of the network, written authorization to release the medical record was obtained, and oncologists were contacted by telephone and asked to mail the chart in its entirety. These charts were then manually audited by the data abstractor at CUMC.

Physician survey—During the baseline interview, subjects provided the names of their surgeon and oncologist, as applicable. These physicians were then contacted via email and postal mail and asked to respond to a survey questionnaire that covered physician demographics (age, race, gender, specialty, training, type of practice), practice characteristics, patient-physician communication style, attitudes towards patient participation in treatment decision making, and propensities to use hormonal therapy and chemotherapy.

Blood and saliva collection and processing

For DNA extraction, either blood samples were collected by venipuncture and shipped overnight to Roswell Park Cancer Institute for processing and storage, and/or 2 cc of saliva was collected using the Oragene DNA Self-Collection Kit. When used, Oragene kits were shipped to Roswell Park within 3 weeks of collection.

At Roswell Park, the blood and saliva samples were processed according to standard protocols. The storage freezers were kept locked, temperature monitored and alarmed.

Genotyping for polymorphisms will be carried out at the conclusion of the study, according to published methods. In most cases, genotyping will be performed using the Illumina Golden Gate for high-throughput multiplexing. We intend to genotype for polymorphisms in drug metabolism pathways, as well as enzymes related to oxidative stress and DNA repair. Relevant polymorphisms will be evaluated in relation to toxicities experienced, as well as dose delays and patient compliance for specific treatment regimens.

Simulation modeling

The B-QUAL study also includes use of an established simulation model (31) to project how observed patterns of adjuvant care translate into population level breast cancer mortality for

the overall sample and for black and white women. Study data will be used to inform model parameter estimates.

Results

Study recruitment ended as of July 31, 2010. Of 1158 patients enrolled in the study, selected demographic characteristics of the 1057 subjects for whom we have chart data are shown in Table 2. Their tumor status and characteristics are detailed in Table 3.

The mean age at diagnosis was 58 years. Fifteen percent of participants were black, 70% white, 8.5% Asian, and 5.0% Hispanic. The majority of women were recruited by KPNC (75%). Two-thirds reported an annual household income greater than \$50,000, and nearly 76% indicated having more than a high school education. Nearly 56% of the women were married, 42% were employed and 32% were retired at time of enrollment. Compared to women of races other than black, black participants were more likely to have been recruited from KPNC ($p < 0.0001$); to report lower annual household incomes ($p < 0.0001$); and to have less than a high school education ($p = 0.0005$). In addition, black participants were less likely to report a positive ER/PR hormonal status ($p = 0.02$), and to have less differentiated tumors ($p = 0.0002$) than women of other races.

With regard to clinical characteristics, 482 patients (45.6%) had stage 1 disease, 757 (73.0%) were node-negative, and 527 (49.9%) initiated adjuvant chemotherapy. More than 60% of tumors were <2 cm in size. Of the 788 patients (76.0%) whose tumors were hormone receptor-positive, 652 (82.7%) initiated hormonal therapy.

All 1158 participants completed the baseline survey that gathered information related to physician communication, attitudes toward adjuvant therapy, decision-making considerations, and pre-treatment expectations. Of enrolled participants, 97.4% and 92.5% have completed follow-up surveys #1 and #2, respectively. These surveys queried participants about treatment satisfaction and experience with symptoms in addition to collecting data related to socioemotional factors such as fatalism, optimism, and social support. Data collection for the hormonal survey is ongoing with 90.1% of participants with hormone receptor positive tumors having completed a survey 6 months post-diagnosis about symptoms related to adjuvant hormonal therapy, treatment satisfaction, and quality of life.

The subjects of this study identified 277 treating physicians who were sent surveys to complete. To date, 51% ($n = 141$) have responded.

Discussion

The American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) have developed quality measures for breast cancer based on clinical impact, scientific acceptability, and usefulness, potential for improvement, reliability, and feasibility. Included are receipt of radiotherapy for women who received breast conserving surgery for localized breast cancer; consideration of adjuvant chemotherapy for women under age 70 with hormone receptor-negative non-metastatic breast cancer; and hormonal therapy for women with hormone receptor-positive breast cancer. The B-QUAL Study was undertaken to explore the reasons for non-receipt of indicated primary adjuvant systemic therapy in women with breast cancer. This large community care study is the first to address suboptimal hormonal treatment and chemotherapy simultaneously.

One key question about breast cancer quality of care has been its role in black-white disparities in breast cancer mortality. Studies have suggested that blacks are less likely to

receive adequate breast cancer therapy. Hence, we have tried to recruit sufficient black patients to be able to compare white and black patients so as to address racial disparities with regard to chemotherapy and hormonal therapy. With 185 black women in our sample (16%) and records on 160 of those to date, we should have sufficient statistical power to address this for most key analyses.

Strengths of the B-QUAL Study include the large sample, diverse geographic representation, community practice settings, high participation rate, and excellent participant retention. In addition, the bio-specimens we have collected enable us to address pharmaco-genetic and other biological factors that may affect compliance and patterns of care. Finally, collaboration with an established simulation modeling group will allow us to project the impact of non-compliance with adjuvant systemic therapy on our ability to meet national goals for reducing cancer mortality in the US.

The B-QUAL Study has adopted a wide-ranging approach to the causes of non-compliance that are encompassed in the bio-psychosocial model (Figure 3). Most factors can be grouped into four categories: patient (age, race, SES, psychological factors, etc), tumor (stage, grade), system (hospital type, insurance), and physician characteristics (gender, race, US vs. foreign trained, type of practice). We also plan to study interactions of these factors with one another as well as with physician-patient communications, treatment toxicity, pharmaco-genomics, and comorbidities.

In the coming months and years, we will be using the collected and accruing data to address these issues and to identify factors that contribute to non-receipt, early discontinuation, or non-adherence to appropriate adjuvant chemotherapy and hormonal therapy in breast cancer. An understanding of the factors that contribute to poor quality of care, especially if differential by race, could suggest interventions to address these problems. For example, if poor communication is a major issue, then physician education or physician extenders may ameliorate the problem. Any intervention would, of course, require testing with regard to its ability to improve compliance and quality of care.

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Figure 1.
B-QUAL study design

Figure 2.

Subject accrual and number of surveys completed (% of enrolled participants) for the B-QUAL Study (details in text)

Note: Accrual and procedures are ongoing.

Figure 3.

Biopsychosocial model which forms the logical rationale for the study design and approach
 ER/PR = estrogen receptor/progesterone receptor

Table 1

Questionnaires/Measures utilized in the B-QUAL Study

Domain	Scale	Phase of administration*
<i>Medical Experiences</i>		
Quality of Life	FACT-B (32)	B, FU1, FU2, HT
Satisfaction with Treatment Decisions (Chemotherapy)	Satisfaction with Decision Scale (33–34)	FU1, FU2, HT
Treatment Satisfaction (Hormonal)	Treatment Satisfaction Questionnaire for Medication (TSQM) (35)	FU1, FU2, HT
Physician-Patient Communication	Communication/Decision-Making (36)	B
Symptoms (Chemotherapy)	Memorial Symptoms Assessment and Taxane scale (37–38)	FU1, FU2
Symptoms (Hormonal therapy)	NSABP Study of Tamoxifen and Raloxifene Symptom Checklist (39)	FU1, FU2, HT
<i>Cognitive</i>		
Medical Literacy	Brief questions used to identify patients with inadequate health literacy (40)	FU1
Patient's pre-Treatment Expectations	Visual Analog Scale (41)	B
Decision-making	Mandelblatt, unpublished	B, FU1, FU2
Medical Mistrust	Group-based Medical Mistrust Scale (42)	FU1
Fatalism	Subscale of Mental Adjustment to Cancer (43)	B
<i>Emotion/Emotion Regulation</i>		
Benefit Finding and Spirituality Scale	Post-traumatic growth inventory (44)	FU2
Religiosity	Santa Clara Strength of Religious Faith Measure (45–46)	FU2
Optimism	Life Orientation Scale (47)	B
Emotion Regulation	Emotional Approach Coping Scale (48)	FU1
<i>Social Relations</i>		
Social Support	MOS Social Support Survey (49)	B
Quality of Care	Interpersonal Processes of Care (50)	FU1, FU2, HT
Stress	Impact of Events(51)	B, FU1, FU2, HT
Attachment Style	Relationship Styles Questionnaire (52)	FU2

Note: B=baseline, FU1=follow-up #1, FU2=follow-up #2, HT= hormonal therapy survey.

Table 2
Demographic characteristics of participants in the B-QUAL study (see text for details)

	All (N=1,057)			Black (N=160)			Other ^a (N=897)			p-value
	M	SD		M	SD		M	SD		
Mean age (years)	58.1	(11.6)		56.8	(11.8)		58.4	(11.6)		0.10
	N	%		N	%		N	%		
Age (n=1057)										
<50	256	24.2		50	31.3		206	23.0		0.08
50 – 59	315	29.8		41	25.6		274	30.6		
60 – 69	310	29.3		48	30.0		262	29.2		
70 – 79	140	13.3		14	8.8		126	14.1		
80+	36	3.4		7	4.4		29	3.2		
Race (n=1057)										
White	740	70.0								
Black	160	15.1								
Asian	90	8.5								
Hispanic	53	5.0								
Other	14	1.3								
Site of recruitment (n=1057)										
CUMC/MSSM	151	14.3		37	23.1		114	12.7		<0.0001
Kaiser	798	75.5		88	55.0		710	79.2		
Henry Ford	108	10.2		35	21.9		73	8.1		
Annual household income (n=1057)										
<25,000	128	12.1		42	26.3		86	9.6		<0.0001
25,000 – 49,999	233	22.0		42	26.3		191	21.3		
50,000 – 89,999	322	30.5		47	29.4		275	30.7		
>90,000	321	30.4		24	15.0		297	33.1		
Refused	53	5.0		5	3.1		48	5.6		

	All (N=1,057)		Black (N=160)		Other ^d (N=897)		p-value
	M	SD	M	SD	M	SD	
Education (n=1056)							
HS graduate	254	24.0	54	33.4	200	22.3	0.0005
College	520	49.2	80	50.0	440	49.1	
Graduate school	282	26.7	26	16.3	256	28.5	
Marital status (n=858)							
Married	480	55.9	60	50.4	420	56.8	0.19
Not married	378	44.1	59	49.6	319	43.2	
Employment status (n=1057)							
Full time	334	31.6	48	30.0	286	31.9	0.24
Part time	111	10.5	11	6.9	100	11.2	
Retired	339	32.1	52	32.5	287	32.0	
Not currently working	273	25.8	49	30.6	224	25.0	

Note: CUMC = Columbia University Medical Center; MSSM = Mount Sinai School of Medicine; KPNC = Kaiser Permanente of Northern California; HFHS = Henry Ford Health System.

^aOther includes White (n= 795), Hispanic (n= 59), Asian (n=102), and other race (n=17)

Table 3
Clinical characteristics of participants in the B-QUAL Study (see text for details)

	All (N=1,057)		Black (N=160)		Other (N=897)		p-value
	N	%	N	%	N	%	
ER/PR Status (n=1037)							
Positive	788	76.0	108	68.8	680	77.3	0.02
Negative	249	24.0	49	31.2	200	22.7	
Grade (n=1057)							
Well differentiated	219	20.7	23	14.4	196	21.9	0.0002
Moderately differentiated	447	42.3	63	39.4	384	42.8	
Poorly differentiated	234	22.1	53	33.1	181	20.2	
Unknown	157	14.9	21	13.1	136	15.2	
AJCC Stage(n=1057)							
I	482	45.6	65	40.6	417	46.5	0.052
II	347	32.8	60	37.5	287	32.0	
III	80	7.6	18	11.3	62	6.9	
Unknown	148	14.0	17	10.6	131	14.6	
Nodes (n=1037)							
Positive	280	27.0	48	30.6	232	26.4	0.27
Negative	757	73.0	109	69.4	648	74.6	
Tumor size (n=931)							
<2 cm	581	62.4	83	56.1	498	63.6	0.09
2 – 5 cm	316	33.9	56	37.8	260	33.2	
>5 cm	34	3.7	9	6.1	25	3.2	
Initiated chemotherapy (n=1057)							
Initiated chemotherapy	527	49.9	87	54.4	440	49.1	0.21
Initiated hormonal therapy (n=788)							
Initiated hormonal therapy	652	82.7	91	84.3	561	82.5	0.65

Note: ER/PR status = estrogen receptor/progesterone receptor status; AJCC = American Joint Committee on Cancer.

^aNon-black includes White (n= 795), Hispanic (n= 59), Asian (n=102), and other race (n=17)