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Non-initiation of adjuvant hormonal therapy in women with hormone receptor positive breast cancer: The Breast Cancer Quality of Care Study (B-QUAL)

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Abstract

Background—Adjuvant hormonal therapy for non-metastatic hormone receptor (HR)-positive breast cancer decreases risk of breast cancer recurrence and increases survival. However, some women do not initiate this life-saving treatment.

Methods—We used a prospective cohort design to investigate factors related to non-initiation of hormonal therapy among women with newly diagnosed, non-metastatic hormone receptor positive breast cancer recruited from three U.S. sites. Serial interviews were conducted at baseline and during treatment to examine sociodemographic factors, tumor characteristics, and treatment decision-making factors. Multivariate modeling assessed associations between variables of interest and hormonal therapy initiation.

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Results—Of 1050 breast cancer patients recruited, 725 (69%) had HR-positive breast cancer, of whom 87 (12.0%) based on self-report and 122 (16.8%) based on medical record/pharmacy fill rates did not initiate hormonal therapy. In a multivariable analysis, non-initiation of hormonal therapy, defined by medical record/pharmacy, was associated with having greater negative beliefs about efficacy of treatment (OR 1.42, 95%CI 1.18-1.70). Non-initiation was less likely in those who found the quality of patient/physician communication to be higher (OR 0.96, 95%CI 0.93-0.99), the hormonal therapy treatment decision an easy one to make (OR 0.45, 95% CI 0.23-0.90) or neither easy nor difficult (OR 0.34, 95%CI 0.20-0.58); and had more positive beliefs about hormonal therapy efficacy (OR 0.40, 95%CI 0.34-0.62).

Conclusions—Factors influencing non-initiation of adjuvant hormonal therapy are complex and influenced by patient beliefs regarding treatment efficacy and side effects. Educational interventions to women about the benefits of hormonal therapy may decrease negative beliefs and increase hormone therapy initiation.

BACKGROUND

Adjuvant therapy (radiation, hormonal therapy (HT), chemotherapy) improves breast cancer survival.[1-2] Despite this, substantial variations occur in the use of these therapies.[3-5] Some patients fail to initiate recommended therapy,[6] delay initiation,[7-9] or discontinue therapy early.[3, 10-11] Any deviations from recommended adjuvant therapy may be associated with a reduction in survival benefit.[3, 7-8] Understanding reasons for non-compliance with treatment recommendations may provide targets for interventions to improve compliance.

Anti-estrogen therapy[12] is widely used as adjuvant treatment of hormone receptor(HR)-positive breast cancers. Tamoxifen reduces risk of recurrence as much as 41% and death by 34%.[2] In postmenopausal women, aromatase inhibitors are even more effective than tamoxifen for decreasing recurrence, increasing survival, and decreasing development of contralateral breast cancer.[13-18]

Despite its efficacy, some women with HR-positive breast cancer do not initiate adjuvant HT[19-24] or fail to complete the recommended 5-year course.[3, 25] Reasons for non-initiation of HT include factors related to the patient, the physician, and patient-physician communication. Prior studies[21, 24, 26] have explored reasons for non-initiation of HT but were limited with regard to study design, generally relying on retrospective database reviews or patient surveys with incomplete patient response resulting in selection bias. Because of the ramifications for morbidity and mortality, non-utilization of adjuvant HT for breast cancer is an important issue.

The Breast Cancer Quality of Care Study (B-QUAL) is a multi-site prospective cohort study of factors associated with suboptimal use of adjuvant chemotherapy and HT in women with early stage breast cancer. Data on non-initiation were either collected prior to non-initiation or in real time as the non-initiation was occurring. Furthermore, we had available pharmacy and medical record data in addition to patient self-report. We present data evaluating the rate of non-initiation of HT. In addition to demographic and clinical factors, this study investigates the impact of psychosocial factors and patient perceptions regarding decision making on non-initiation of HT.

METHODS

Details of the B-QUAL study have been described elsewhere.[27] Briefly, between 2006-2010, women >20 years with newly diagnosed, histologically-confirmed, primary breast cancer, stages I-III, were recruited from three sites (Columbia University Medical Center and Mount Sinai School of Medicine (CUMC/MSSM) in New York City, Kaiser-

Permanente of Northern California (KPNC), and Henry Ford Health Systems (HFHS) in Detroit). Participants were enrolled after diagnosis. For those who received chemotherapy, enrollment was prior to initiation of the third cycle of chemotherapy; otherwise, it was within 12 weeks of diagnosis. Women who were non-English speaking, had a prior history of cancer (except non-melanoma skin cancer), or without access to a telephone were excluded.

Patients participated in phone interviews at the following time points: baseline at or shortly after diagnosis, 4-8 weeks and 12-24 weeks following the baseline interview. For those who self-reported that their tumor was HR-positive or whose physician had discussed and/or prescribed adjuvant HT, additional interviews were conducted every 6 months for the first 2 years and annually thereafter until conclusion of the study. Women determined by medical chart abstraction to have HR-positive breast cancer were included in this analysis.

The primary outcome measure was initiation of hormone therapy as defined by medical record review (a combination of electronic pharmacy records or medical chart abstraction). Sensitivity analyses were performed classifying HT initiation by self-report and also by electronic pharmacy records only in the subset from HFHS and KPNC that had electronic pharmacy records available (87.2% of subjects). Self-report of initiation was determined by asking if a physician had ever discussed or prescribed HT, and if a decision regarding HT was made. The questions were only asked if they answered yes to having a discussion or after they said no at all 3 time points.

Research assistants with previous public health research and interviewing experience conducted the interviews. All research personnel completed mandated training in research with human subjects and all were HIPAA-certified. The study was approved by the Institutional Review Boards of each site and the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) and Human Research Protection Office (HRPO). Written informed consent and HIPAA authorization were obtained from patients prior to study initiation.

Study variables

Demographic, tumor and treatment measures—From the baseline survey, self-reported information included sociodemographic characteristics (age, race/ethnicity, education, annual household income, employment, marital status). Tumor characteristics from the medical record included AJCC disease stage (I, II, III, or unknown), grade (well, moderately, poorly differentiated), nodal status (positive or negative), and tumor size. Charlson Comorbidity Index[28] score was calculated from the number of comorbidities reported 12 months prior to diagnosis up to 3 months after diagnosis. Factors related to treatment were obtained by self-report and included receipt of adjuvant chemotherapy, referral to a medical oncologist, whether the participant was under the care of a medical oncologist, and if HT was discussed.

Individual roles in decision-making—To determine decision-making, five statements were presented that displayed varying amounts of physician and patient input to the adjuvant treatment decision (e.g., “The doctor should make the decision…” to “You should make the decision…”) and were modified from a validated questionnaire by Llewellyn-Thomas.[29] The perceived level of difficulty in making the treatment decision was assessed using a 5-point Likert scale ranging from 1=*extremely difficult* to 5=*very easy*. Participants were also asked if someone, other than their physician, helped them in making their HT treatment decision and who that person was.

Patient-physician communication—A measure of patient-physician communication quality was comprised of 5 items and evaluated the extent to which the participant agreed (1=*very strongly disagree* through 6=*very strongly agree*) with statements regarding the sufficiency of information provided by the physician upon which to base a treatment decision; whether the benefits and risks of HT were explained adequately; if the doctor solicited the patient's opinion regarding treatment; and whether the physician believed the participant's comorbidities precluded adjuvant therapy.

Decision-making factors—Decision-making considerations included physical considerations (2 items; physical appearance and nausea and vomiting), the negative decisional balance (5 items; e.g., "thinking hormonal therapy is not always effective"), positive decisional balance (3 items; e.g., "being able to worry less about the cancer coming back"), concrete considerations (4 items; e.g., "finances and the ability to pay for treatment"), and influence of family and friends (1 item).[30] Participants were then asked to state whether the item was an important consideration in their decision regarding HT.

Social support was determined using the Medical Outcomes Study (MOS) Social Support Survey[31] and by assessing the number of close friends and relatives in whom the participant confided. Attitudes toward HT were determined using a 7-item scale. Participants were asked the extent to which they agreed with statements such as "Hormonal therapy does not help you live longer". Likert responses ranged from 1=*not at all* to 4=*very much*.

Data analysis

Comparison between HT initiators and non-initiators was conducted using Fisher's or Chi-square tests for categorical variables and Student's t-tests for continuous variables. Cronbach's alpha was used to assess internal consistency and reliability of scale measures. We conducted multivariate logistic regression analyses to assess the relationship between demographic characteristics, clinical characteristics, treatment received, decision-making scales, patient-physician communication scales, and psychosocial factors with HT non-initiation. Assuming 80% power, 0.05 type I error, and a conservative 50% "exposure" to the variable of interest in the non-initiators, the initiation rate of 16.8% in the current sample allows for the detection of an odds ratio of roughly 1.285 (or 0.715). All analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC).

RESULTS

We identified 1362 women with newly diagnosed non-metastatic breast cancer between May 2006 and June 2010. Of these, 110 (10.5%) refused to participate while 202 (14.8%) were found to be ineligible. Of the 1050 women who participated, 725 (69.0%) had HR-positive breast cancer. Non-initiation of HT was found in 16.8% (n=122) of the subjects by medical record and 12% (n=87) when defined by self-report. Overall, 69 women were non-initiators by both methods, while 585 were initiators by both methods, giving an agreement rate for both methods of 654/725 or 90.2% and a kappa statistic of agreement of 0.61. There were 53 women who were non-initiators by medical record but initiated by self-report, and 18 who initiated by medical record but not by self-report. Within the group defined by medical records, the subset defined by electronic pharmacy record only (n=632) had an initiation rate of 17.9% (n=113). The baseline characteristics of this subset were similar to the overall group (Table 1).

Older age, KPNC site of recruitment, positive nodes, and no chemotherapy were associated with non-initiation of HT (Table 1). Additionally, using self-report, lower household income (p=0.0007), not being employed (p=0.005), being unmarried (p=0.023), and stage I

(p=0.006) were also associated with non-initiation. Self-reported race was not a contributing factor to non-initiation.

Several treatment, decision-making, communication, and psychosocial factors were associated with HT initiation as defined by both medical record and self-report (Table 2). Non-initiators were less likely to report having discussed HT with a physician; preferred to have more personal input with equal or less physician involvement in the treatment decision; and reported an average lower quality of communication with their physicians than did HT initiators. Non-initiators were also more likely to state that the physical and negative considerations surrounding HT (Cronbach's alpha=0.75) were relatively important and that the positive considerations were less important (Cronbach's alpha=0.66) relative to HT initiators and were less likely to have favorable attitudes towards HT.

Using the medical record to define initiation, non-initiators reported greater difficulty making their HT treatment decision (p<0.001) and had a lower level of social support (4.1 [SD 0.6] vs. 4.3 [SD 0.7], p=0.04). Using self-report to define initiation, non-initiators reported being under the care of a medical oncologist slightly less often (91% vs. 99%, p=0.01), and reported having a husband/partner help with the HT treatment decision less often (40% vs. 56%, p=0.03) compared to HT initiators.

In multivariable regression analysis (Table 3), HT non-initiation was associated with age >80 years, and with greater negative beliefs about the efficacy of treatment (e.g., thinking HT is not always effective). Non-initiation of HT was less likely in women with stage II breast cancer; those who found the HT decision an easy one to make; and those having positive beliefs about HT (e.g., being able to worry less about the cancer recurring).

Using the medical record to define initiation, non-initiators were less likely to have considered the HT treatment decision neither difficult nor easy (OR 0.45, 95%CI 0.23-0.90) or to have assessed communication with their physician about treatment to be higher quality with regard to sufficiency of information (OR 0.96, 95%CI 0.93-0.99). Using self-report, non-initiation of HT was more likely among black women (OR 2.94, 95%CI 1.47-5.85), those who thought the patient should make the HT treatment decision (OR 2.19, 95%CI 1.08-4.46); and those who more heavily weighed the physical considerations of treatment (OR 2.89, 95%CI 1.26-6.63). Non-initiation was less likely among those who received chemotherapy (OR 0.50, 95%CI 0.25-0.99) and among participants that discussed HT with a physician (OR 0.16, 95%CI 0.04-0.65. Participants from the three recruitment sites did not differ, and are compared in Appendix A. Interaction terms with recruitment site were examined in multivariate analysis, but none were statistically significant (data not shown).

DISCUSSION

Despite the profound benefits of adjuvant HT, we found that, depending on the method used to define HT initiation, between 12.0% and 17.9% of subjects did not initiate HT. Like other studies, we found that increasing age, stage of disease, beliefs about HT, and the level of decision-making difficulty were associated with non-initiation.[21, 24, 26] While some of these factors are associated with non-adherence to hormonal therapy in women that initiate treatment, our study is one of the first to delve into the decisions and behaviors associated with non-initiation.

As we have seen, variability in the literature exists as a function of the methods used to define initiation.[21-23, 26, 35-36] Among studies that use self-report to define initiation, the non-initiation rates ranged from 13.6% to 19%,[22, 26] whereas, for chart abstraction or pharmacy prescription fill rates, non-initiation ranged between 14.0% and 30.0%.[21, 23] Evidence suggests, that self-reported medication use tends to over-estimate compliance

compared to more objective measures, such as pill counts and pharmacy records.[37] Studies that used self-report tended to recruit subjects later in their disease and interview them by phone, which may have introduced selection bias into the sample population, possibly biasing towards those who were more compliant. We found a 5% difference in the rates of HT non-initiation, with 17% for medical records and 12% for self-report. However, the results of analyzing with both definitions were very similar.

We found an overall rate of 90.2% agreement (kappa=0.61) between self-report and medical record. A recent study[38] found an agreement rate between self-report and medical records of 94% while another smaller study[32] found an agreement rate of 96%. We found that 18 subjects had a record of a prescription for HT or a pharmacy fill for the prescription (14/18 from pharmacy records, 4 from medical record review) but the patient did not report taking HT. It is possible that the patient filled the prescription but never took the drug. An additional 53 patients reported taking HT but had no record of a prescription being written or filled. The prescription may have been written but not recorded in the chart, or some may have obtained their medication through an outside pharmacy, e.g., through a spouse's plan.

We found that among non-initiators the decision to forego adjuvant HT was not an easy one. In recent years, there has been a shift towards more active patient participation in treatment decisions. However, for this to occur successfully, patients must be provided with information about treatment options by their health care providers that would allow a truly informed decision about their care[35, 39] and that information is best received when provided in a manner consistent with patient values and personal preferences.[40-41] Increasing physician participation in treatment decision-making, encouraging questions, and active patient participation has been shown to improve patient's comprehension, lead to better compliance, and improve treatment satisfaction.[42] To maximize effectiveness, interventions to improve adherence should be multifactorial and involve behavioral modification through reinforcement while increasing convenience of care in addition to providing educational information.[37]

Cancer treatment decisions are complex. Willingness to undergo treatment is based on a deliberative evaluation process.[43] One study of patient beliefs related to prescription medications for chronic illness concluded that patients mentally conduct a cost-benefit analysis; those who perceived a higher necessity for the medication reported higher adherence, while those with more concerns were less adherent.[44] Adherence to HT once initiated is also associated with belief in the efficacy of the medication[21, 26] and with belief in the benefits of taking prescribed medications.[36, 44-46] Women are more adherent to HT prescriptions received from a medical oncologist than to those received from a surgeon,[5] perhaps because oncologists convey greater confidence in the efficacy of HT.[21, 26, 47-48]

We did not find associations between non-initiation of HT and several sociodemographic factors, including race, that previously were reported to influence compliance.[20-21, 49] This may reflect insufficient statistical power or a strong correlation between these factors and the behavioral factors assessed. Despite this limitation, our study is one of the larger multicenter prospective studies examining patient-reported reasons for HT non-initiation.

A study strength was that it utilized breast cancer patients from multiple institutions with different health care systems from around the country, lending increased generalizability to the results. Furthermore, the study subjects were recruited prospectively at the time of breast cancer diagnosis or shortly thereafter; thus, most of the data collected was in advance of the decisions regarding HT initiation, though they were generally aware that a decision was to be made, generally several weeks/months after diagnosis. In addition, our estimate of HT

utilization may have been more valid and less biased than self-report, which is usually utilized.

Our study had other limitations as well. Most of the patients came from managed health care plans and were insured so we could not explore the impact of insurance on non-initiation. There were undoubtedly unmeasured variables that may have played a role in non-initiation, such as the distribution of medication samples, although this probably occurred infrequently as the majority of subjects were enrolled in a health care system that covered the cost of prescription medication. Our measure of HT initiation was based on electronic pharmacy for the 87.2% of patients in KPNC and HFHS, but for those patients in NYC without a prescription plan, we used data from medical records. While this may have overestimated initiation, this should not have had a significant influence on the findings. Although the current measure of HT non-initiation is better than self-report data, using electronic pharmacy records is also an imperfect measure. Another possibility is that some of the patients could have filled their HT prescriptions outside the KPNC or HFHS prescription plans; however, this is known to be an infrequent phenomenon.[49] There was a 5% difference between the patient-reported rate of non-initiation and the rate we reported using the prescription plans so use of an outside plan should not have been greater than this and was probably considerably less. The lack of association with race may have been related to small sample size.

In conclusion, in this prospective cohort study of women with early stage breast cancer, we found a significant proportion of women with HR-positive breast cancer do not initiate HT, despite the majority having access to treatment. The main factors associated with non-initiation are ones that can be modified by interventions. The perception of poor physician-patient communication, negative beliefs regarding efficacy of the medication and fear of toxicities may be reversed with educational interventions. New initiatives, such as ASCO's Quality Oncology Practice Initiative, may also be used in the future to improve initiation and adherence. Improving how information about HT is conveyed to patients has the potential to improve breast cancer outcomes.

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Table 1

Demographic, tumor, and clinical characteristics of B-QUAL participants with hormone receptor positive breast cancer.

	Total (n =725)		Self Report (n=725)					Medical Record (n=725)					Electronic Pharmacy Records (n=632)				
			HT 88.0% (n=638)		HT 82.1% (n=519)		HT 82.1% (n=519)	HT 82.1% (n=519)		No HT 16.8% (n=122)		P value	HT 82.1% (n=519)		No HT 17.9% (n=113)		P value
	N	%	N	%	N	%		N	%	N	%		N	%	N	%	
Age							<0.0001					0.009					0.04
<40	30	4	29	5	1	1		27	5	3	2		18	3	3	3	
40 – 49	126	17	111	17	15	17		107	18	19	16		83	16	17	15	
50 – 59	207	29	189	30	18	21		173	29	34	28		146	28	29	26	
60 – 69	222	31	204	32	18	21		193	32	29	24		172	33	27	24	
70 – 79	113	16	88	14	25	29		85	14	28	23		82	16	28	25	
80+	27	4	17	3	10	11		18	3	9	7		18	3	9	8	
Race							0.20					0.45					0.53
White	539	74	482	76	57	66		453	75	86	70		398	77	81	72	
Black	89	12	73	11	16	18		74	12	15	12		51	10	12	11	
Asian	56	8	47	7	9	10		43	7	13	11		42	8	13	12	
Hispanic	32	4	29	5	3	3		27	4	5	4		22	4	4	4	
Other	9	1	7	1	2	2		6	6	3	2		6	1	3	3	
Educational level							0.11					0.21					0.18
≤ HS graduate	169	23	150	24	19	22		142	24	27	22		120	23	23	20	
College	355	49	304	48	51	59		287	48	68	56		250	48	65	58	
Graduate School	201	28	184	29	17	20		174	29	27	22		149	29	25	22	
Annual household income							0.0007					0.14					0.11
<15,000 – 24,999	94	13	73	11	21	24		73	12	21	17		51	10	18	16	
25,000 – 49,999	148	20	128	20	20	23		122	20	26	21		110	21	25	22	
50,000 – 89,999	220	30	204	32	16	18		187	31	33	27		171	33	30	27	

	Total (n =725)		Self Report (n=725)					Medical Record (n=725)					Electronic Pharmacy Records (n=632)				
			HT 88.0% (n=638)		HT 82.1% (n=519)		HT 82.1% (n=519)	HT 82.1% (n=519)		No HT 16.8% (n=122)		P value	HT 82.1% (n=519)		No HT 17.9% (n=113)		P value
	N	%	N	%	N	%		N	%	N	%		N	%	N	%	
>90,000	227	31	205	32	22	25		195	32	32	26		165	32	31	27	
Refused answer	36	5	28	4	8	9		26	4	10	8		22	4	9	8	
Employment status							0.005					0.38					0.60
Full time	214	30	195	31	19	22		183	30	31	25		147	28	27	24	
Part time	90	12	80	13	10	11		76	13	14	11		62	12	13	12	
Retired	254	35	209	33	45	52		203	34	51	42		195	38	50	44	
Not currently Working	167	23	154	24	13	15		141	23	26	21		115	22	23	20	
Marital status							0.023					0.16					0.09
Married	386	53	313	49	44	51		329	55	57	47		307	59	55	49	
Not married	317	44	240	38	40	46		258	43	59	48		208	40	56	50	
Unknown	22	3	85	13	3	3		16	3	6	27		4	1	2	2	
Recruitment site							0.04					0.03					0.09
CUMC/MSSM[a]	93	13	89	14	4	5		84	14	9	7		-	-	-	-	
KPNC[b]	545	75	472	74	73	84		442	73	103	84		442	85	103	91	
HFHS[c]	87	12	77	12	10	11		77	13	10	8		77	15	10	9	
AJCC stage							0.006					0.17					0.12
I	380	52	321	50	59	68		309	51	71	58		265	51	69	61	
II	246	34	230	36	16	18		213	35	33	27		185	36	28	25	
III	63	9	57	9	6	7		54	9	9	7		43	8	8	7	
Unknown	36	5	30	5	6	7		27	4	9	7		26	5	8	7	
Grade							0.14					0.29					0.24
Well differentiated	193	27	165	26	28	32		155	26	38	31		136	26	37	33	

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	Total (n =725)		Self Report (n=725)					Medical Record (n=725)					Electronic Pharmacy Records (n=632)				
			HT 88.0% (n=638)		HT 82.1% (n=519)		HT 82.1% (n=519)	HT 82.1% (n=519)		No HT 16.8% (n=122)		P value	HT 82.1% (n=519)		No HT 17.9% (n=113)		P value
	N	%	N	%	N	%		N	%	N	%		N	%	N	%	
Mod. differentiated	363	50	329	52	34	39		309	51	54	44		264	51	50	44	
Poorly differentiated	112	15	97	15	15	17		95	16	17	14		77	15	13	12	
Unknown	57	8	47	7	10	11		44	7	13	11		42	8	13	12	
Nodes							0.0003					0.005					0.004
Positive	213	29	202	32	11	13		190	31	23	19		157	30	19	17	
Negative	512	71	436	68	76	87		413	69	99	81		362	70	94	83	
Tumor size							0.67					0.79					0.86
<2 cm	457	63	398	62	59	68		381	63	76	62		325	63	72	64	
2-5 cm	218	30	196	31	22	25		183	30	35	29		158	30	31	27	
>5 cm	23	3	21	3	2	2		18	3	5	4		15	3	4	4	
Missing	27	4	23	4	4	5		21	3	6	5		21	4	6	5	
Comorbidities							0.08					0.155					0.09
<2	652	90	579	91	73	84		548	91	104	85		470	91	95	84	
≥2	70	10	56	9	14	16		53	9	17	14		48	9	17	15	
Missing	3	<1	3	<1	0	0		2	<1	1	1		1	<1	1	1	
Received chemotherapy							<0.0001					0.025					0.10
Yes	310	43	302	47	19	22		269	45	41	34		223	43	39	35	
No	415	47	336	53	68	78		334	55	81	66		296	57	74	65	

Note: HT = hormone therapy. HS grad = high school graduate. AJCC = American Joint Committee on Cancer.

p-value based on Chi-square statistic

[a]CUMC/MSSM = Columbia University Medical Center/Mount Sinai School of Medicine in New York City.

[b]KPNC = Kaiser Permanente of Northern California.

[c]HFHS = Henry Ford Health System in Detroit, Michigan

Table 2

Factors related to the initiation of HT among B-QUAL participants with hormone-sensitive breast cancer.

	Total (n =725)		Self Report					Medical Record				
			HT 88.0% (n=638)		No HT 12.0% (n=87)		P value	HT 83.2% (n=603)		No HT 16.8% (n=122)		P value
	N	%	N	%	N	%		N	%	N	%	
HT treatment-related												
Referred to medical oncologist	696	96	615	96	81	93	0.14	580	96	116	95	0.57
Under the care of a medical oncologist	714	98	631	99	83	95	0.01	595	96	119	98	0.35
Ever discussed HT with any physician	709	98	630	99	79	91	<0.001	594	99	115	94	0.004
HT decision-making												
HT treatment decision-making beliefs												
Doctor should make the decision	20	3	20	3	0	0		19	3	1	1	
Doctor should make decision considering the patient's opinion	169	23	154	24	15	17		146	24	23	19	
Doctor and patient make the decision together	272	38	238	37	34	39	0.0014	222	37	50	41	0.016
Patient should make the decision considering the doctor's opinion	230	32	203	32	27	31		194	32	36	30	
Patient should make the decision	34	5	23	4	11	13		22	4	12	10	
Level of decision-making difficulty							0.81					<0.001
Difficult	131	18	530	83	75	86		94	16	37	30	
Neither difficult nor easy	115	16	60	9	7	8		97	16	18	15	
Easy	427	59	31	5	4	5		376	62	51	42	
No response	52	7	17	3	1	1		36	6	16	13	
Other than MD, had help with making decision about HT*	391	54	349	55	42	48	0.30	331	55	60	49	0.25
Who Helped:												
Husband/partner	212	54	195	56	17	40	0.03	184	56	28	47	0.09
Parent/child/grandchild	122	31	104	30	18	43	0.29	101	31	21	35	0.90

	Total (n =725)		Self Report					Medical Record				
			HT 88.0% (n=638)		No HT 12.0% (n=87)		P value	HT 83.2% (n=603)		No HT 16.8% (n=122)		P value
	N	%	N	%	N	%		N	%	N	%	
Other relative	100	26	86	25	14	33	0.51	80	24	20	33	0.36
Other medical professional	13	3	13	4	0	0	0.38	13	4	0	0	0.10
	Mean	SD	Mean	SD	Mean	SD	P value	Mean	SD	Mean	SD	P value
HT related patient-physician communication												
Communication quality scale[1]	27.9	7.0	28.3	6.8	25.0	8.1	0.0004	28.4	6.7	25.5	8.2	0.0004
Psychosocial												
Decision making considerations												
Physical	0.6	0.5	0.6	0.5	0.8	0.4	<0.0001	0.6	0.5	0.7	0.5	0.04
Negative balance	1.0	1.3	0.9	1.2	2.2	1.4	<0.0001	0.9	1.2	1.7	1.5	<0.0001
Positive balance	2.7	0.7	2.8	0.5	2.0	1.1	<0.0001	2.8	0.6	2.3	1.0	<0.0001
Concrete considerations	0.7	1.0	0.7	1.0	0.8	1.0	0.31	0.7	1.0	0.8	1.0	0.41
MOS** Social Support[1]	4.3	0.7	4.3	0.7	4.2	0.7	0.32	4.3	0.6	4.1	0.7	0.04
Attitudes about HT[2]	2.9	0.5	3.0	0.5	2.5	0.6	<0.0001	3.0	0.5	2.7	0.6	0.0005
Family and friends involved in decision	0.3	0.5	0.3	0.5	0.3	0.5	0.73	0.3	0.5	0.4	0.5	0.44
Number of close friends/relatives	13.7	11.3	13.6	10.9	14.2	13.6	0.65	13.6	10.5	14.1	14.5	0.71

p-value based on Chi-square statistic

*More than one response possible, total is greater than 100%.

**Medical Outcomes Study measure of social support.

[1]Communication quality scale, range 5-30 with higher scores indicating greater perceived quality of patient-physician communication.

[2]MOS social support index, range1 to 5, where 5 is more social support.

[3]Measure of attitude towards hormonal therapy, range 1 to 5 scale, where 5 is more positive.

Table 3

Multivariate analysis of demographics, clinical characteristics, treatment-related, decision-making, patient-physician communication, and psychosocial factors associated with non-initiation of HT among B-QUAL participants with hormone receptor-positive breast cancer (N=725).

	Self Report 12.0%			Medical Record 16.8%		
	OR	**95% CI**	**P value**	**OR**	**95% CI**	**P value**
Age						
<40	Ref	--	--	Ref	--	--
40 – 49	3.44	(0.41 – 28.5)	0.25	1.67	(0.45 – 6.25)	0.45
50 – 59	2.07	(0.25 – 17.0)	0.50	1.77	(0.49 – 6.41)	0.38
60 – 69	1.71	(0.21 – 14.2)	0.62	1.43	(0.39 – 5.29)	0.59
70 – 79	5.90	(0.70 – 49.5)	0.10	3.28	(0.86 – 12.5)	0.08
80+	**10.5**	**(1.10 – 99.6)**	**0.04**	**4.94**	**(1.07 – 22.9)**	**0.04**
Race						
White	Ref	-	-	Ref	--	--
Black	**2.94**	**(1.47 – 5.85)**	**0.002**	1.47	(0.77 – 2.80)	0.24
Asian	1.97	(0.86 – 4.50)	0.11	1.72	(0.86 – 3.44)	0.12
Hispanic	1.27	(0.35 – 4.61)	0.72	1.09	(0.40 – 3.03)	0.86
Other	2.43	(0.43 – 13.9)	0.32	2.71	(0.63 – 11.7)	0.18
Recruitment site						
CUMC/MSSM[a]	Ref	-	-	Ref	--	--
KPNC[b]	2.80	(0.95 – 8.27)	0.06	1.82	(0.85 – 3.87)	0.12
HFHS[c]	1.61	(0.46 – 5.67)	0.46	0.88	(0.33 – 2.35)	0.79
AJCC stage						
I	Ref	-	-	Ref	---	--
II	**0.42**	**(0.21 – 0.81)**	**0.01**	**0.59**	**(0.35 – 0.98)**	**0.04**
III	0.82	(0.29 – 2.34)	0.71	0.59	(0.25 – 1.39)	0.23
nUknown	1.11	(0.41 – 3.02)	0.84	1.25	(0.54 – 2.89)	0.61
Comorbidities						

	Self Report 12.0%			Medical Record 16.8%		
	OR	**95% CI**	**P value**	**OR**	**95% CI**	**P value**
<2	Ref	-	-	Ref	--	--
≥2	0.65	(0.32 – 1.30)	0.22	1.50	(0.81 – 2.80)	0.20
Received chemotherapy	**0.50**	**(0.25 – 0.99)**	**0.05**	1.21	(0.72 – 2.04)	0.47
HT treatment related and decision-making						
Ever discussed HT with any physician	**0.16**	**(0.04 – 0.65)**	**0.01**	0.48	(0.14 – 1.59)	0.23
HT treatment decision-making beliefs						
Doctor should make the decision	Ref	--	--	Ref	--	--
Doctor and patient should make the decision together	1.91	(0.94 – 3.89)	0.08	1.56	(0.88 – 2.75)	0.13
Patient should make the decision	**2.19**	**(1.08 – 4.46)**	**0.03**	1.65	(0.93 – 2.92)	0.09
Level of decision-making difficulty						
Difficult	Ref	--	--	Ref	--	--
Neither difficult nor easy	0.77	(0.36 – 1.64)	0.50	**0.45**	**(0.23 – 0.90)**	**0.02**
Easy	**0.23**	**(0.12 – 0.43)**	**<0.001**	**0.34**	**(0.20 – 0.58)**	**<0.0001**
Did not respond	0.75	(0.28 – 2.00)	0.56	0.71	(0.31 – 1.66)	0.43
HT patient-physician communication						
Communication quality scale	0.98	(0.94 – 1.02)	0.34	0.96	(0.93 – 0.99)	0.03
HT Decision making considerations						
Physical	**2.89**	**(1.26 – 6.63)**	**0.01**	1.12	0.65 – 1.95	0.68
Negative balance	**1.74**	**(1.40 – 2.18)**	**<0.0001**	**1.42**	**1.18 – 1.70**	**0.0002**
Positive balance	**0.37**	**(0.36 – 0.54)**	**<0.0001**	**0.40**	**0.34 – 0.62**	**<0.0001**
MOS * Social Support	0.89	(0.57 – 1.40)	0.89	0.73	0.52 – 1.04	0.08
Attitudes about HT	0.57	(0.32 – 1.03)	0.06	0.80	0.50 – 1.30	0.37

* Medical Outcomes Study measure of social support