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Adherence to the National Quality Forum (NQF) Breast Cancer Measures Within Cancer Clinical Trials: A Review From ACOSOG Z0010

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Abstract

Background—In 2007, the National Quality Forum (NQF) released four performance measures for the treatment of breast cancer. We proposed to study the degree of adherence with these measures among participating institutions in a multi-institutional trial.

Methods—American College of Surgeons Oncology Group (ACOSOG) Z0010 enrolled breast cancer patients onto a phase II trial studying the prognostic significance of bone marrow and sentinel node micrometastases. The current study used χ^2 analyses to determine the degree of adherence with four NQF measures among three institution types: academic, community, and teaching affiliate.

Results—The study revealed small but important differences in two measures. Ninety-five percent of patients from teaching affiliated institutions received whole-breast radiation compared to 92% at academic and 91% at community hospitals. Among patients who were underinsured or uninsured, a marked decrease in radiation use was noted in comparison to patients with insurance—85 versus 93%, respectively. The study also revealed a difference among institutional types in patients undergoing excisional biopsy for diagnosis. In teaching-affiliated hospitals, 28.6% underwent excisional biopsy as compared to 36.8 and 37.4% in academic and community hospitals, respectively. There was no statistically significant difference between adherence rates with the remaining two measures. Adjuvant chemotherapy was administered to patients with hormone receptor negative tumors ≥ 1 cm in size in 79–85% of institutions. Tamoxifen was administered to 79–82% of those patients with hormone receptor-positive cancers.

Conclusions—Among breast cancer patients enrolled onto a multi-institutional clinical trial, we found a high degree of adherence with current consensus standards for adjuvant treatment, despite varied practice environments.

Breast cancer is a major public health issue, with more than 1 million individuals diagnosed annually worldwide. Because many guidelines have been developed for breast cancer treatment, various interest groups have set forth to or are currently evaluating quality measures for the care of patients with breast malignancies.¹ Some of the entities interested in performance measures surrounding the diagnosis, treatment, and outcomes of individuals with breast cancer include the American Society of Clinical Oncology (ASCO), the American Society of Breast Surgeons (ASBS), the National Accreditation Program of Breast Centers (NAPBC), the National Comprehensive Cancer Network (NCCN), and the National Quality Forum (NQF).^{2–6} Several international groups have also recently published their quality initiative programs for measuring and assessing the care delivered to those with breast cancer.^{7–9} Each of these multidisciplinary groups is focused on identifying a key set of measures that assess the breast cancer patient at defined time points in the care delivery process. These measures are largely derived from evidence-based reviews by consensus and expert panels, which assess the performance measures in relation to their impact on disease-free and overall survival.^{5,10}

The number of quality measures set forth by different groups varies from 4 to 30.^{5,11,12} The measures set forth by NQF, and endorsed by ASCO and NCCN, for breast cancer reflect the rich history of randomized, controlled trials performed to test novel treatments and assess clinical outcomes. The three primary NQF measures in breast cancer are: (1) compliance with radiation administered within 1 year of diagnosis for women aged <70 years receiving breast-conserving surgery, (2) compliance with adjuvant chemotherapy considered or administered within 4 months of diagnosis for women aged <70 with American Joint Committee on Cancer (AJCC) T1c, stage II or III hormone receptor–negative breast cancer, and (3) compliance with adjuvant hormone therapy (Tamoxifen or a third-generation aromatase inhibitor) considered or administered within 1 year of diagnosis for patients with AJCC T1c, stage II or III hormone receptor–positive breast cancer.¹³

A fourth measure, compliance with needle biopsy to establish the diagnosis of cancer preceding surgical excision/resection, is endorsed for surveillance but is not recommended for accountability or public reporting.

American College of Surgeons Oncology Group (ACO-SOG) Z0010 was a multi-institutional phase II trial evaluating the prevalence and prognostic significance of sentinel node and bone marrow micrometastases in patients with T1 or T2 N0 M0 breast cancer. The trial opened in 1999 and closed after completing accrual of 5539 patients in 2003. We hypothesized that a high adherence rate to the four NQF measures would be seen among Z0010 subjects despite the variety of enrolling institutions and a treatment time frame that predated the NQF measurement recommendations. Whole-breast radiation therapy after breast-conservation surgery was dictated within the protocol and is consistent with the first NQF measurement (radiation within a year of diagnosis); however, the remaining adjuvant treatment decisions were left to the discretion of the treating surgeons and medical oncologists. In general, we believed that patients enrolled onto a clinical trial would receive high-quality treatment aside from what is specified in the protocol.

PATIENTS AND METHODS

Study Design

The schema and primary aims for ACOSOG Z0010 have been previously published.^{14–16} This prospective nonrandomized trial was approved by the National Cancer Institute (NCI) and the institutional review board of each participating institution before the initiation of patient accrual. Each patient signed an informed consent before registration. Patients with clinical stage I/II breast carcinoma planned for breast-conservation treatment underwent surgical resection of the primary tumor and sentinel lymph node biopsy. Patients requiring a

mastectomy were not eligible to participate in Z0010; however, some patients enrolled onto this trial did undergo mastectomy when negative resection margins could not be obtained with breast-conserving surgery. Whole-breast radiotherapy (45 to 50 Gy) was dictated within the postoperative treatment plan.

Data on use of adjuvant therapies (radiation and systemic therapy) were collected at the 18-month postsurgery visit. These 18-month data were used in the analysis of radiotherapy, hormone therapy, and chemotherapy as a substitute for the timelines laid out for these therapies by the NQF.

Participating Institutions

One hundred ninety-eight surgeons from 126 institutions participated in ACOSOG Z0010.¹⁶ Each surgeon or surgeon group enrolling patients onto Z0010 self-reported their institutional type as academic, teaching affiliated, or community. Institutions were classified as Commission on Cancer (CoC) or NCCN hospitals through identification from the American College of Surgeons or NCCN Web sites. The reported use of adjuvant therapy was compiled from the 18-month follow-up for each patient.

Statistics

Frequency distributions were used to describe the characteristics of the patients and institutions. The adherence rate for each of the four NQF measures was computed (number of patients for which the recommended measure was applied divided by the total number of patients), and χ^2 analyses were performed to determine the differences in adherence rates among the three institution types: academic, community, and teaching affiliate. All statistical analyses were performed by SAS statistical analysis software (SAS Institute, Cary, NC).

RESULTS

The demographic information for patients enrolled onto ACOSOG Z0010 have been previously published.¹⁴ Of the 5327 patients with data that could be evaluated, 4477 (84%) were ≤ 70 years old, and 3956 (74%) had pathologically confirmed T1 tumors. Among the 126 participating institutions, 85 (67%) were CoC-approved institutions and 14 (11%) were NCCN institutions. Of the patients enrolled onto Z0010, 2659 (49.9%) were recruited from an academic institution, 1211 (22.7%) from a teaching-affiliated institution, and 1409 (26.5%) from a community hospital. Forty-eight patients (0.9%) were entered from an institution type other than those described, including international and military institutions.

For evaluation of the first NQF measure, compliance with radiation administered within 1 year of diagnosis for patients aged < 70 who underwent breast conservation, a total of 3497 patients had data that could be evaluated for the 18-month visit. We were missing adjuvant therapy information at follow-up for 852 patients because it was not initially collected as part of the trial. As shown in Table 1, $> 92\%$ of patients enrolled onto ACOSOG Z0010 received whole-breast radiation after breast-conservation surgery. Patients treated at academic centers (92.4%) and community hospitals (90.9%) had a statistically significant lower rate of receiving radiotherapy compared to those treated at teaching affiliated institutions (95.2%) ($P = 0.003$). More notable and clinically important, patients who were insured through Medicaid and those who did not have insurance were less likely to receive radiotherapy (85.2%) compared with those in the privately insured group (92.9%) ($P = 0.0007$).

The second NQF measure is compliance with adjuvant chemotherapy offered within 120 days to patients aged < 70 who have tumors that are ≥ 1 cm in size and that are hormone receptor negative. Information was not gathered from Z0010 participants regarding whether a patient

was offered chemotherapy and refused. Therefore, it was only possible for us to identify those patients who did receive chemotherapy. A total of 638 patients were eligible for chemotherapy by criteria; however 124 did not have hormone receptor information available or were lost to follow-up and were therefore excluded from analysis. Although we noted differences in the proportion of patients who received chemotherapy among the different institution types, these differences did not reach statistical significance. When patients were stratified by age, we noted that older patients were less likely to receive chemotherapy than their younger counterparts ($P = 0.0132$) (Table 2).

Assessment of the third NQF measure, compliance with adjuvant hormone therapy, revealed that 80.1% of patients with hormone receptor–positive breast cancers were receiving postoperative Tamoxifen therapy at their 18-month follow-up visit. This analysis included 2305 patients, with 461 of the total accrued eligible women having insufficient clinical information. There were no statistically significant differences in the proportion of patients receiving Tamoxifen among the different types of institutions. However, when aromatase inhibitors were included as a type of hormone therapy, patients at community hospitals were more likely to receive adjuvant hormone therapy—Tamoxifen or an aromatase inhibitor ($P = 0.0238$)—in comparison to patients treated at the academic or teaching-affiliated hospitals (Table 3).

The fourth NQF measure, compliance with needle biopsy for diagnosis versus surgical excision, is a surveillance measure and is not used for accountability or public reporting at this time. In Z0010, 4582 patients had data at registration regarding their type of cancer diagnosis. For 743 patients of the total accrued patients, these data could not be evaluated. As demonstrated in Table 4, 35.3% of patients underwent surgical excision for diagnosis of their breast cancer. Among the different institutional types, those patients from a teaching-affiliated hospital had a significantly lower excisional biopsy rate at 28.6% ($P = 0.0001$). Younger patients, primarily those aged <40, were more likely to undergo excisional biopsy for their breast cancer diagnosis (44.2% vs. 33–37%, $P = 0.01$).

DISCUSSION

Clinical trial databases represent a potentially important tool for assessing compliance with recommended quality measures and determining the next quality measures of importance. ACOSOG is the most recent group to join the NCI-supported cancer cooperative trials group and represents a unique compilation of surgeons and institutions from across the United States. ACOSOG Z0010 is the largest prospective trial to date reported from this cooperative group. Patients registered on Z0010 came from a heterogeneous set of institutions, none of which was preselected. However, skills verification requirements were necessary for participation by individual surgeons. There are currently 21 NCCN institutions nationwide, 14 of which enrolled patients onto Z0010. CoC-accredited hospitals are those that have met peer-reviewed guidelines for comprehensive, multidisciplinary cancer care. Sixty-seven percent of patients from Z0010 were treated in CoC-approved institutions. The CoC reports that approximately 75% of newly diagnosed cancer patients in the United States are treated within accredited locations.¹⁷ The Z0010 database therefore contains a representative sample of early-stage breast cancer patients treated both within large comprehensive cancer centers and those treated in local hospitals without a cancer-designated focus.

This study represents what is to our knowledge the first review of a clinical trials database to determine compliance with national quality measures in patients with breast cancer. The selected NQF measures, endorsed by ASCO and NCCN, reflect the outcomes of previous clinical trials showing a survival benefit for patients receiving adjuvant radiation, chemotherapy, and hormone therapy.^{18–20} Although teaching-affiliated hospitals represented

the smallest subset of patients enrolled (22.7%) onto this trial, individuals treated at these locations had the highest rates of adjuvant radiotherapy (95.2%), adjuvant chemotherapy (7.9%), and adjuvant Tamoxifen therapy (81.6%). In addition, patients from these treating institutions had the lowest rates of excisional biopsy for diagnosis (28.6%). One possible explanation for this finding is that patients treated in these affiliated hospitals may be less likely to move between hospitals and providers, and their outcomes may be more centralized and retrievable. Although there were statistically significant differences in two NQF measures across institution types, they were very similar with respect to adherence to the reportable measures. The statistical differences are likely due to the large sample sizes available for the radiation and excisional biopsy measures within the ACOSOG Z0010 database.

Compliance with the first NQF measure, whole-breast radiotherapy, was the highest among all three institutional types (90.9–95%). Other reviews have shown similar rates of adherence to this quality measure. A recent analysis of the Medicare–Surveillance, Epidemiology, and End Results Program (SEER) database from 2000 to 2002 revealed 94% compliance with postoperative radiotherapy in 3674 women between the ages of 66 and 70.²¹ Data from eight NCCN centers collected between 1997 and 2002 revealed a 94% compliance with radiation recommendations for patients with stage I or II breast cancer.²² Statistically significant factors in this data set associated with a lower use of radiation included comorbid illnesses, tubular histology, type of health insurance, and actual NCCN institution. Although our patient population included only 135 patients with Medicaid or lack of insurance coverage, there was a statistically significantly lower proportion of patients receiving radiotherapy in this subgroup. Perhaps a closer look at patients not receiving radiotherapy would help determine the obstacles for the compliance of recommended care.

The number of measurement points needed to assess the treatment of the breast cancer patient is unknown. Measures that show a high degree of compliance, such as radiotherapy after breast-conserving surgery, may not be cost-effective to continue to evaluate. However, the definition of “high” has not been established and may vary on the basis of the stakeholders involved. It is not known whether 100% compliance would be achievable. The National Initiative for Cancer Care Quality (NICCQ) led by ASCO developed a set of 36 breast cancer measures through expert review of established guidelines, review articles, and randomized, controlled trials. Through patient surveys and medical record review, NICCQ documented <85% compliance with 18 of 36 measures.¹¹ This ACO-SOG Z0010 data review identified a similarly moderate (80–81%) compliance with two of the recommended measures, chemotherapy for endocrine nonresponsive tumors and hormone therapy for those with endocrine-responsive disease. The NICCQ outcomes revealed a wide range of compliance with chemotherapy (60–91%) and a smaller range for hormone therapy (85–95%).¹¹ Explanations for lower compliance rates in each of these data sets include the difficulty in assessing the patients’ understanding of the recommendations and/or desire to avoid side effects from adjuvant therapy and their comorbid illnesses that may have affected the ability of their providers to offer and administer additional treatment. Future quality-of-life outcome studies may help in better understanding the noncompliance with these measures.

In an international trial of 1378 breast cancer patients treated from 1998 to 2005, Cheng and colleagues found that 100% adherence to 10 quality indicators offered statistical improvements in overall survival (hazard ratio, 0.46) in comparison to those patients who did not have 100% compliance.⁷ Included in the 10 quality measures were radiotherapy for breast-conservation patients and hormone therapy for patients with endocrine-responsive disease. Chemotherapy was recommended only for patients aged <50 with node-positive disease. Patients with stage I disease in this subset (479) had a 5-year progression-free survival of 93% if they had 100% adherence versus 87% for <100% adherence to 10 quality measures. The ability to have 100% adherence will be dependent on the health care delivery system, its financial structure, the

patients' and physicians' biases and preferences, and behavioral practices within the community itself.⁷

The only system evaluating the use of clinical trials as a benchmark of quality care is the voluntary reporting system developed in Germany.⁹ A nationwide breast cancer quality-care initiative was developed in 2002 and tracked yearly until the most recent publication in 2007. Eleven quality indicators were recorded, and over time, each showed improvement in patient compliance. Interestingly, adherence was high for endocrine therapy use (93%), while compliance with chemotherapy had a progressive increase from 65 to 81% with tracking and feedback to the institutions. The established benchmark for patients to be enrolled onto clinical trials is 10–20%, and 7% of patients met this measure in 2007 in Germany. Currently, there are no reported breast cancer measuring systems in the United States that use clinical trial enrollment as a marker of quality care.

There are limitations to this secondary review of a prospective clinical trial's database. Only one of the NQF quality measures was included as an integral part of the Z0010 trial (radiation after breast-conserving surgery). In addition, there was patient movement between institutions. Some patients may have had their surgery at one location and follow-up at another outpatient clinic. The complete record of adjuvant treatments administered may not have been identified by the enrolling surgeon. Additionally, this data set reflects the care received 18 months after registration. We are unable to definitely prove that the radiotherapy was provided within the recommended 12 months or that the chemotherapy, if indicated, was started within the 4-month window after surgery. As with any database, we are limited by what we are asking and how diligent the investigators are in retrieving and reporting accurate data. Fortunately, these data are audited, and although every patient encounter cannot be reviewed, many are, and they are then compared to source documentation to assure compliance within the clinical trial protocol guidelines.

Unlike other medical conditions, the outcomes for patients with cancer have been recorded for over three decades in cancer registries as well as clinical trial databases. Patients within cancer clinical trials have helped to establish the current quality of care measures. As more patients are treated with novel therapies, undergo evaluation with genomic predictors, and are diagnosed with innovative imaging techniques, the quality measures will continue to change. The patients enrolled onto the Z0010 trial showed a high degree of compliance with quality standards that were not yet defined at the time they received treatment. Clinical trial databases afford another means to evaluate our current standards and the patient populations/institutions that may benefit the most from quality review and education. Further trials exploring NQF measures are warranted to better assess the overall impact of the measures on patient care.

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TABLE 1NQF standard 1: compliance with whole-breast irradiation (WBI)^a by institution and insurance type

Variable	WBI, <i>n</i> (%)	No WBI, <i>n</i> (%)	<i>P</i>
Institution type ^b			0.0030
Academic	1708 (92.4%)	140 (7.5%)	
Community	810 (90.9%)	81 (9.1%)	
Teaching affiliate	722 (95.2%)	36 (4.8%)	
Insurance type ^c			0.0007
Insured	3116 (92.9%)	237 (7.1%)	
Medicaid/none	115 (85.2%)	20 (14.8%)	

^aIncludes data for patients aged <70 and excludes those known to have had mastectomy^bWBI data missing for 852 patients^cWBI or insurance data missing for 861 patients

TABLE 2NQF standard 2: compliance with adjuvant chemotherapy^a by institution type and age

Variable	Chemotherapy, <i>n</i> (%)	No chemotherapy, <i>n</i> (%)	<i>P</i>
Institution type ^b			0.3935
Academic	223 (82.9%)	46 (17.1%)	
Community	119 (81.5%)	27 (18.5%)	
Teaching affiliate	87 (87.9%)	12 (12.1%)	
Age (year)			0.0132
<30	8 (88.9%)	1 (11.1%)	
30–39	53 (93.0%)	4 (7.9%)	
40–49	148 (86.6%)	23 (13.4%)	
50–59	142 (83.0%)	29 (17.0%)	
60–69	78 (73.6%)	28 (26.4%)	

^aTable includes data for patients aged <70 who are ER negative and who have path tumor size of ≥ 1 cm

^bChemotherapy data missing for 124 patients

TABLE 3NQF standard 3: compliance with adjuvant hormone therapy^a by institution and therapy type

Variable	Hormone therapy, <i>n</i> (%)	No hormone therapy, <i>n</i> (%)	<i>P</i>
All hormone types			
Institution type ^b			0.0238
Academic	913 (80.7%)	219 (19.3%)	
Community	525 (85.8%)	87 (14.2%)	
Teaching affiliate	467 (83.2%)	94 (16.8%)	
Tamoxifen and selective estrogen modulators			
Institution type			0.2429
Academic	891 (78.7%)	241 (21.3%)	
Community	498 (81.4%)	113 (18.6%)	
Teaching affiliate	458 (81.6%)	103 (18.4%)	

^aTable includes data for patients aged <70 who are ER positive and who have path tumor size ≥1 cm^bHormone therapy data missing for 461 patients

TABLE 4NQF standard 4: compliance with needle biopsy for diagnosis^a by institution type and age

Variable	No excision, <i>n</i> (%)	Excision, <i>n</i> (%)	<i>P</i>
Institution type ^b			0.0001
Academic	1433 (63.2%)	835 (36.8%)	
Community	840 (62.6%)	502 (37.4%)	
Teaching affiliate	694 (71.4%)	278 (28.6%)	
Age (year)			0.0139
<30	19 (55.9%)	15 (44.1%)	
30–39	140 (55.6%)	112 (44.4%)	
40–49	633 (63.1%)	370 (36.9%)	
50–59	953 (65.8%)	496 (34.2%)	
60–69	737 (66.5%)	371 (33.5%)	
≥70	485 (65.9%)	251 (34.1%)	

^aThe study's CRF asks the question, "Was cancer excised for diagnosis?" We interpreted an answer of "no" to this question to indicate that a needle (rather than excisional) biopsy was performed

^bExcision data missing for 124 patients