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Modifying And Validating A Quality Of Life Measure to Fit Your Patient Population

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Abstract

Introduction: A well-developed quality of life (QoL) instrument is valuable in identifying the burden of illness. We were interested in exploring whether existing QoL instruments were suitable for patients in our medical setting and, if not, whether this could be rectified by adapting an existing valid and reliable instrument to meet the specific needs of our patient population. For the purposes of this study, we chose to evaluate the quality of life of patients with breast cancer. Specifically, we were interested in two aspects of QoL in women with breast cancer. The first was whether existing instruments were pertinent to the women in our venue. The second research interest was dependent upon the first. If current instruments were found wanting, could this be rectified through the creation and validation of new domains of relevance to these patients?

Method: First, five patients were interviewed to ascertain QoL issues pertinent to women in our medical setting. Second, to determine regional appropriateness of existing breast cancer QoL instruments, a search was conducted to identify and review existing breast cancer specific QoL instruments. Third, an addendum was created (to be used in conjunction with an existing instrument identified through the search) that contained three QoL domains not typically found: Financial, Spirituality and Satisfaction with Medical Care. The addendum was then tested along with an existing instrument (FACT-B).

Results: Internal consistency for the new scales, Satisfaction with Medical Care, Spirituality, and Financial had alpha coefficients of 0.81, 0.80, and 0.63 respectively. The total score for FACT-B plus addendum was 0.69. Pearson's correlation coefficients were 0.49 for Financial, 0.64 for Satisfaction with Medical Care, and 0.70 for Spirituality. Total test/retest was 0.71.

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Modifying and Validating A Quality Of Life Measure to Fit Your Patient Population

Quality of life (QoL) means different things to different people. Consequently, measuring QoL is a subjective task and no universal definition for the term has been developed (Olschewski, Schulgen, Schumacher, Altman, 1995). Schipper and Levitt (1985) reported that the most difficult aspect of evaluating QoL is defining what is to be measured. However, the majority of QoL instruments incorporate at least three domains in response to the World Health Organization's (WHO) definition of health: "Health is a state of complete physical, mental, and social well-being, and not merely the absence of disease and infirmity (WHO, 1947)." Moreover, Olschewski et al. (1995) reported that most QoL researchers agree that the QoL construct is multidimensional and that well-developed instruments should assess a patient's emotional, social and physical well-being. In addition to incorporating the aforementioned domains, we believe that a well-developed QoL instrument should meet six criteria (Table 1).

For the purposes of this study, we chose to evaluate the quality of life of patients with breast cancer. The [National Cancer Institute](#) (2006) reported that 12.7% of U.S. women will develop breast cancer at some time in their lives. Breast cancer is the second leading of cause of cancer death (after lung cancer) of women in the US and, excluding skin cancer, the most commonly found cancer in women (American Cancer Society, 2005). In Georgia, breast cancer is the leading cause of death among women and accounts for 32% of all new cancer cases. It estimated that 4,520 women will develop breast cancer in the state of Georgia in 2007.

The ACS estimates that 88% of those diagnosed with breast cancer will survive five years after diagnosis, 80% will survive after ten years, 71% will survive after 15

years and 63% after 20 years (ACS, 2005). As survival rates are increasing, the medical community has recognized the need to evaluate the impact of breast cancer on the quality of this survival rather than concentrate solely on typical outcome measures such as tumor response, time to progression, and disease-free survival (Levine, Guyatt, Gent, 1988). Additionally, as treatments for breast cancer become more complex and aggressive, the need to evaluate the impact of these treatments on a patient's quality of life has been deemed necessary as well. Thus, a well-developed QoL instrument is valuable in identifying the burden of illness associated with breast cancer and serves to guide caregivers about optimizing treatment plans for patients.

We were interested in two aspects of QoL in women with breast cancer. The first was whether existing instruments were pertinent to the women in our venue. The second research interest was dependent upon the first. If current instruments were found wanting, could this be rectified through the creation and validation of new domains of relevance to these patients?

The geographical and social context of our work was that of a large academic medical center (AMC) in Augusta Georgia - a region of the country widely acknowledged to face a number of socioeconomic challenges and also recognized by many to have a populous with deep-seated religious faith.

The authors did not intend to develop a new QoL instrument but rather to adapt an existing validated questionnaire to become institutionally competent. Olschewski et al reported, "If one feels that important specific aspects are missing in a particular questionnaire, it is in most cases possible to add additional components to the existing measuring

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Table 1*Core domains and criteria for QoL instruments*

DOMAIN		
1.	Physical health	The physical health domain usually refers to the patient's assessment of pain, ability to provide self-care, degree of mobility and response to treatment side effects.
2.	Mental health	The mental health domain examines emotional and cognitive well-being such as depression, anxiety, fear, concentration, and memory. This domain may also include issues related to self-esteem and body image.
3.	Social health	The social domain assesses the patient's relationships with a significant other, family members, friends and colleagues.
CRITERIA		
1.	Psychometric properties: a. Reliability b. Validity	<p>a. Reliability: Tests for reliability should establish the instrument's ability to yield stable scores over time (for stable patients) and to ensure that items are highly correlated.</p> <p>b. Validity: The instrument should also possess varying types of validity (i.e., measuring what is intended to be measured). Types of validity include:</p> <ul style="list-style-type: none"> i. Content validity (i.e., the ability to cover the content domains of the construct). ii. Face validity (i.e., the ability to measure what is important to patients). iii. Predictive validity (i.e., the ability to predict factors that determine a patient's QoL). iv. Criterion validity (i.e., the ability to demonstrate the measure correlates with a "gold standard").^{4,5,7}
2.	Responsiveness	The instrument should be able to respond to changes in a patient's condition.
3.	Short recall	The instrument should minimize recall bias by assessing recent time periods. Asking a patient to recall periods longer than four weeks is not recommended.
4.	Balanced questions	The instrument should contain both positive and negative items. A quality of life instrument should strive to measure positive changes (e.g., renewed sense of spirituality) as well as negative changes (e.g., physical discomfort) that occur in the course of the disease and its treatment.
5.	User-friendliness	The instrument should be short and designed for patient-administration (i.e., the survey tool should be able to be completed in 10 to 20 minutes for a patient of average literacy).
6.	Patient perceptions	The instrument should measure the patient's perception of his or her own quality of life and not the physician's perception of the patient's quality of life.

instrument without changing its original structure." Therefore, we set out to assess the appropriateness of existing measures for our patient population and (based on these findings) develop an

addendum to the most appropriate existing instrument. Our ultimate goal was to address the specific needs of breast cancer patients in our institution.

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METHOD PHASE I

Participants

Five women participated in the interview process. Women were deemed eligible for the interview if they met the following criteria: (a) at least 18 years of age, (b) had a diagnosis of breast cancer, (c) had no underlying psychiatric illness or other cancer diagnosis, (e) were able to speak, read, and understand English, and (f) willing to participate in the study.

Design and Procedure

Semi-structured interviews were conducted with five patients with varying stages of breast cancer to ascertain QoL domains relevant to breast cancer patients in our institution. Spouses or friends of the patients were also invited to participate in the interviews.

Results

From the interviews, it became apparent that QoL measures should incorporate more than the three domains as outlined by the WHO. All five patients raised the issue of religion and/or spirituality and most voiced financial concerns. Another area of concern was the stigmatization that often results after a cancer diagnosis and the desire for friends and family members to abstain from treating them differently. It was also recommended that the medical community strive to “listen better” and offer compassion and emotional support to patients, particularly to those women who had little or no social support. The findings from the interviews resulted in the development of an addendum that contained three additional domains relating to financial well-being, satisfaction with medical care and spirituality.

The financial well-being sub-scale contains five items that addresses the impact breast cancer has on financial stability as well as ability to afford

expenses related to the disease. Six questions were added to address satisfaction with medical care and seven questions were added to address whether breast cancer had a positive or negative effect on spirituality. Five-point Likert scales were used for all three additional domains in the addendum ranging from 0 (Not at all) to 4 (Very much). (Table 2)

METHOD PHASE II

Design and Procedure

A search of medical and social sciences electronic databases using the keywords “breast cancer,” “quality of life” “questionnaire” and “instrument” was conducted to identify existing breast cancer specific QoL instruments.

Results

Five quality of life measures relevant to this study and specific to breast cancer were found. These instruments were reviewed to ascertain their ability to meet basic design requirements as well as their ability to address the issues gleaned from the patient interviews (Table 3).

The authors determined that the FACT-B most closely fit the desired criteria as a validated, user-friendly QoL tool for breast cancer. The FACT-B has well-established reliability and validity and has demonstrated ability to assess change in performance status. The instrument contains both positive (e.g., I am able to enjoy life) and negative (e.g., I feel sad) items and can be completed in 10 minutes [Brady, Cella, Mo, Bonomi, Tulskey, Lloyd, Deasy, Cobleigh, Shimoto, 1997].

METHOD PHASE III

Participants

Participants were 39 patients with varying stages of breast cancer who were currently undergoing treatment at the AMC. Thirty-two (82%) of the women

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Table 2

Addendum to FACT-B

"Place a mark in one box to indicate how true each statement has been for you in the past seven days."

DOMAIN	NOT AT ALL	A LITTLE BIT	SOMEWHAT	QUITE A BIT	VERY MUCH
<i>Financial well-being</i>					
• I have difficulty dealing with my health insurance company. (R)					
• I am able to pay for travel expenses related to my medical appointments (e.g., gas, hotel, food).					
• I am able to afford items I would like to have as a result of my illness (e.g., wigs, prosthesis, special food).					
• I have difficulty obtaining health, disability or life insurance. (R)					
• I am able to financially support myself and my family.					
<i>Satisfaction with medical care</i>					
• I feel comfortable communicating with my doctors and nurses about my illness and treatment.					
• I am inconvenienced as a result of waiting to receive medical care. (R)					
• My doctors and nurses offer me compassion and emotional support.					
• The hospital staff (e.g., receptionists, lab technicians, etc.) treat me in a pleasant manner.					
• My doctors and nurses communicate clearly with me concerning my illness and treatment.					
• I am satisfied with my overall medical care.					
<i>Spiritual well-being</i>					
• I attend worship services.					
• I pray or meditate.					
• Maintaining my religious/spiritual beliefs has been difficult since discovering my illness. (R)					
• I have found (or renewed) a belief system since discovering my illness.					
• My belief system offers me comfort .					
• I have hope for my future.					
• Due to my illness, I have made positive changes in my life.					

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Table 3

Overview of existing Breast Cancer QoL instruments relevant to the study

Number of survey items	Data collection method (time to complete)	Survey origins	Survey integrity	Gaps in survey
1. Quality of Life - Breast Cancer Version [Ferrell & Grant]				
46	Self-report	Developed to measure physical, psychological, social and spiritual well-being of breast cancer patients.	Reliability and validity of the instrument were established with a mail survey to 686 members from the National Coalition for Cancer Survivorship (294 were breast cancer survivors).	Does not address quality of care and contains one question concerning financial well-being. Survey tested on breast cancer survivors. Therefore, use with newly diagnosed or treated patients may be questionable.
2. Breast Cancer Chemotherapy Questionnaire (BCQ) [Levine, Guyatt, Gent, 1988]				
30	Administered by interviewer (10-15 minutes)	Developed to measure the impact of adjuvant chemotherapy for patients in clinical trials with stage II breast cancer.	Established reliability and validity components.	Does not address issues pertaining to financial or spiritual well-being. Additional burden on faculty and staff due to mode of administration.
3. European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer (EORTC-QLQ-BR23) [Aronson, et al., 1993]				
23	Self-report	Designed to accompany a 30-item core tool (EORTC-QLQ-C30) that assesses five functional scales (physical, role, cognitive, emotional and social), three symptom scales (nausea, pain, fatigue) and a global QoL dimension.	Designed for use in international settings.	Cross-cultural reliability and validity of the instrument have not yet been established. The instrument does not address spirituality or satisfaction with medical care.
4. The Breast Cancer Quality of Life Scale [Gordon, 2000]				
273	Self-report (35 minutes)	Addresses social, financial, spiritual, psychological, physical, and sexual well-being as well as quality of medical care. Measures positive and negative aspects of breast cancer.	Adequate reliability and validity. Further refinement needed.	Compliance may become an issue when administering a survey that requires 35 minutes for completion.
5. Functional Assessment of Cancer Therapy Scale with Breast Cancer Module (FACT-B) [Brady, et al., 1997]				
36	Self-report (10 minutes)	FACT-G assesses a patient's physical, social, emotional and functional well-being. Breast cancer module has nine additional items FACT-G (27) + Breast cancer module (9) = FACT-B.	Reliability and validity of the FACT G have been well established. Appeal of the FACT-G is that it is a general cancer module that can be adapted with various reliable and valid subscales (e.g., lung, prostate and others).	Does not address spirituality, satisfaction with medical care or financial concerns.

Table 4*Demographic and Clinical Characteristics of study population (Phase III)*

CHARACTERISTIC	RESULTS	
	Number	%
Race		
Caucasian	22	56
African American	15	39
Not stated	2	5
Age (years)		
Mean	51.6	-
Standard deviation	12.3	-
Range	25.0 - 80.0	-
Education level		
High School or GED	19	49
Trade or Technical School	7	18
Some College	6	15
College Degree	3	8
Graduate Degree	2	5
Missing	2	5
Income		
Under \$10,000	15	39
\$10,001-\$25,000	10	25
\$25,001-\$50,000	10	25
\$50,001-\$75,000	3	8
Data not stated	1	2
Marital Status		
Single	5	13
Single (with significant other)	2	5
Separated	3	8
Divorced	6	15
Widowed	8	20
Married	14	36
Data not stated	1	3
Clinical Status		
Early Breast Cancer	16	41
Metastatic Breast Cancer	16	41
Inflammatory Breast Cancer	3	8
Recurrent Breast Cancer	1	3
Data not stated	3	8

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Table 5

FACT-B plus Addendum: Internal Consistency/Test-Retest

DOMAIN	COEFFICIENT ALPHA	TEST/RETEST
FACT-G		
• Physical (7-items)	.88	.64
• Social (10-items)	.79	.85
• Emotional (6-items)	.76	.74
• Functional (7-items)	.82	.86
<i>"B" component of FACT</i>		
• Additional Concerns (Breast) (9-items)	.71	.83
Cultural competence Addendum		
• Financial (5-items)	.63	.49
• Satisfaction with Medical Care (6-items)	.81	.64
• Spirituality (7-items)	.80	.70
Summary data		
• FACT-B total score	.72	.64
• Addendum total score	.75	.71
• FACT-B plus addendum total score	.69	.71

agreed to complete the survey again at a second visit. All respondents were ambulatory.

Demographic data for the study patients describe a population that is 60% Caucasian and 40% African American, mean age 52 years (range 25-80), 70% had a high school or technical school diploma, and two-thirds (66%) had an annual income of less than \$25,000 per year. (Table 4)

Patients were deemed eligible for Phase III of study if they met the same eligibility criteria as those outlined for Phase I.

Materials

Once screened and written informed consent was documented, three instruments were administered to each patient: (a) a baseline demographic questionnaire, (b) the established FACT-B survey instrument and (c) the regionally appropriate addendum to FACT-B developed by the investigators. The baseline demographic questionnaire obtained information regarding age, race/ethnicity, educational level, household income, marital status, and assessment of clinical status.

Design and Procedure

Patients were asked to read each question and indicate how true each statement had been for them during the previous seven days. All patients completed the measure during an outpatient clinic visit. At all times, a study investigator was available to answer any questions or concerns. Questionnaires were generally completed between 10 and 15 minutes. To assess test/retest reliability, patients were asked to complete the FACT-B and the addendum again at their next visit, approximately three-to-four weeks later.

RESULTS*Reliability*

Alpha coefficients for all sub-scales of the FACT-B ranged from 0.71 to 0.88. As all subscales were above .70, these scales can be considered reliable. The Satisfaction with Medical Care and Spirituality subscales of the addendum had alpha coefficients of 0.81 and 0.80 respectively, indicating acceptable internal consistency. The Financial sub-scale had an alpha coefficient of 0.63. Alpha coefficients for FACT-B (0.72) and Addendum (0.75) can be considered reliable. The FACT-B plus addendum had a reliability score of .0.69. Pearson's correlation coefficients for sub-scales of the FACT-B ranged from 0.64 to 0.86. Test/Retest correlations for the Financial, Satisfaction with Medical Care, and Spirituality subscales of the Addendum were .49, .64, and .70 respectively. Test/Retest FACT-B total score was 0.64, Addendum was 0.71 and FACT-B plus addendum was 0.71. (Table 5).

Validity

Two measures of validity were used to determine extent to which the instrument measured the concept of QoL in breast cancer patients. The first method involved content validity and included a review of items by a panel of researchers to include psychologists and medical oncologists. The second method involved correlating the FACT-B plus

addendum with the FACT-B. There was a moderate to strong correlation between FACT-B and FACT-B plus addendum ($r = 0.78$). (Table 5).

DISCUSSION

The literature is replete with evidence that breast cancer screening and treatment centers should endeavor to listen to and respond to issues and concerns raised by their constituents (Hamilton, et al., 2003, Emens and Davidson, 2003, Rust, 2003). In aspects of care that range from ease of clinic scheduling to expanding car parking facilities to enhanced patient knowledge of post-treatment risks of recurrence, patients represent a fundamental, yet often overlooked, source of knowledge and ideas as to how to improve the standard of care.

For women with breast cancer, this research created a QoL tool that, upon initial evaluation, appears relevant for patients in our institution. On receipt of a diagnosis of breast cancer, women enter a "medical world" where they are confronted with new terminology, potentially conflicting information and advice, a myriad of medical and surgical therapeutic options, and almost certainly, less-than-certain, potentially life altering, decision-making points (Freedman, 2003).

It is within this context that physicians must develop a trusting, caring relationship that facilitates the delivery of the appropriate and needed healthcare services. A key component of this relationship is successful provider-patient communication. To that end, the FACT-B plus our addendum provides a catalyst to this relationship.

The authors recognize a variety of limitations to this research. First, our sample size was limited. Second, our patient population was somewhat skewed towards the lower end of the socioeconomic strata (both in economic and educational terms) and may not represent issues pertinent to women in higher socioeconomic groups. Third, all data is self-report and comes with a range of limitations in terms of accuracy and honesty.

Notwithstanding the limitations, the study may offer value to individuals attempting to

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measure the quality of life of their patients without having to "reinvent the wheel" by creating a brand new instrument. Future studies could examine the utility of adapting and validating existing measures to meet the needs of women in various regions, stages of breast cancer or for women in different racial and ethnic groups.

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