

Financial Toxicity Among Women With Metastatic Breast Cancer

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OBJECTIVES: To determine the incidence of financial toxicity among women with metastatic breast cancer, as well as the relationships among financial toxicity, quality of life, and overall cancer-related distress in members of this patient population.

SAMPLE & SETTING: 145 women with metastatic breast cancer receiving care at an urban outpatient breast cancer clinic.

METHODS & VARIABLES: A cross-sectional analysis of women with metastatic breast cancer was performed. Data were collected on patient characteristics, quality of life, cancer-related distress, and financial toxicity using self-administered questionnaires.

RESULTS: Financial toxicity is common among women with metastatic breast cancer and more common among low-income women with the disease. In addition, financial toxicity is correlated with worse quality of life and overall cancer-related distress.

IMPLICATIONS FOR NURSING: Nurses should consider financial toxicity for all patients receiving treatment for cancer. Understanding the concerns of specific patient populations and patients with different stages of cancer is necessary to tailor assessment and mitigation strategies.

KEYWORDS metastatic breast cancer; financial toxicity; cancer-related distress; quality of life

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Financial toxicity, defined as adverse economic consequences resulting from medical treatment, is established as an important burden and source of distress in cancer care (Khera, 2014; Zafar & Abernethy, 2013a, 2013b; Zafar et al., 2013). In addition, financial toxicity has been documented in multiple malignancies, as well as across cancer stages and income levels (Buzaglo et al., 2015; de Souza & Yap, 2014; Jaggi et al., 2014; Khera et al., 2014; Lathan et al., 2016; Yabroff et al., 2016). The term financial toxicity is used with intent in cancer care, creating an equivalency with other toxic and devastating side effects of cancer diagnosis and treatment. The relationship between cancer care and financial toxicity is complex. A conceptual framework created by the National Cancer Institute (2018) relates numerous factors to financial toxicity, including illness status, insurance, medical and nonmedical costs, and treatment choices, which can eventually affect health and financial outcomes. Additional factors influencing the financial toxicity of cancer include out-of-pocket costs, such as co-payments, over-the-counter medications and supplies, childcare, transportation, parking, and meals; loss of income may also occur as a result of cancer diagnosis and treatment (Zafar et al., 2013).

Insurance coverage choices can contribute to financial toxicity during cancer care. The Patient Protection and Affordable Care Act (PPACA) has significantly affected health care since its implementation in 2010. As of May 2018, the number of people in the United States without health insurance was 15.5%, which is up from 12.7% in 2016, but still lower than the high of 16% in 2010, prior to the implementation of the PPACA (Cohen, 2018). Although more individuals in the United States have access to care with the PPACA, in many cases there has been increased cost sharing. Cost sharing is particularly

acute with policies chosen for lower monthly cost but, conversely, higher costs associated with actual illness (Thorpe, Allen, & Joski, 2015). Fees are invoiced to the patient as an additional specific co-payment at time of service or as percentages of total care. This cost sharing has serious implications for all patients with cancer but particularly for patients with progressive chronic illness treated during a long period of time (e.g., metastatic breast cancer). The financial impact of a potential PPACA repeal, replacement, or refinement will need to be defined for patients and families with cancer (Eltorai & Eltorai, 2017).

Even in early-stage disease, cancer care across the illness continuum is chronic and expensive, characterized by multiple types and rounds of treatment. During treatment and into survivorship, patients with cancer and their families are more vulnerable to financial problems and at higher risk for bankruptcy and financial distress than patients with other chronic illnesses (Ramsey et al., 2013; Zafar et al., 2013). This toxicity then forces budgetary limitations for patients and families that include not only leisure activities and education (e.g., children's private school or college tuition), but also everyday essentials, such as food, clothing, prescription medication, and even long-term cancer therapies (Bradley et al., 2007; Kent et al., 2013; Zheng et al., 2017). In the United States, financial toxicity is more severe for African Americans (Pisu et al., 2015). Non-White, female, and younger individuals with cancer are more likely to experience financial distress to the point of bankruptcy, with implications for overall cancer survival (Ramsey et al., 2016).

Although all patients with cancer are vulnerable to financial toxicity, patients with advanced or metastatic cancer appear to be particularly susceptible. The paradigm for metastatic cancer treatment is often sequential and involves expensive chemotherapy or immunotherapy that lasts several months to years. Diagnosis of this chronic progressive illness and its resulting treatment has unique financial implications because of the chronicity of therapy, cumulative treatment-associated costs, ongoing out-of-pocket expenses, and maintenance of employment while undergoing therapy and having declining health (Gallups, Copeland, & Rosenzweig, 2017).

Since 2014, measurement of the financial toxicity of cancer has primarily been assessed using a patient-reported outcome tool, the Comprehensive Score for Financial Toxicity (COST) measure (de Souza et al., 2017). The psychometric properties of the COST tool have been validated, ensuring that the tool measures

financial toxicity as a unique construct (de Souza et al., 2017); it has been incorporated into cancer research as a validated measure of financial toxicity resulting from cancer diagnosis and treatment.

Background

Breast cancer is the most common cancer and the second leading cause of cancer-related death among women in the United States (American Cancer Society, 2017). However, an increasing number of women in the United States are living with metastatic breast cancer, likely because of improvements to treatment and aging of the population. It is anticipated that 168,292 women with metastatic breast cancer will be alive in 2020, which is a 31% increase from 2010 (Mariotto, Etzioni, Hurlbert, Penberthy, & Mayer, 2017; Thientosapol et al., 2013).

A high degree of heterogeneity exists regarding treatment for metastatic breast cancer. The National Comprehensive Cancer Network ([NCCN], 2018) recommends that sequential chemotherapy be continued until the patient with metastatic breast cancer has poor performance status or has had no response to three sequential chemotherapy regimens without clinical response.

Patients with metastatic cancer may overestimate the likelihood of curative results from palliative chemotherapy (Weeks et al., 2012). Such overestimation may be attributable to the heterogeneity in metastatic breast cancer treatment response. Chemotherapy for metastatic breast cancer is often given sequentially for several courses and typically until the patient is close to the end of life. Women with metastatic breast cancer are more likely to receive intensive care and chemotherapy within two weeks of death and less likely to receive hospice services compared to other patients with advanced solid tumors (Shin et al., 2016). The impact of income status at the time of metastatic breast cancer diagnosis on financial toxicity, quality of life, and cancer-related distress is not known.

The purpose of this study was to assess financial toxicity, including specific financial concerns, among patients with metastatic breast cancer. A secondary purpose was to determine the effect of financial toxicity on quality of life and cancer-related distress outcomes, overall and by income level.

Methods and Variables

Sample and Setting

From March to July 2016, a cross-sectional assessment of financial toxicity among women with

metastatic breast cancer receiving care at an urban outpatient breast cancer clinic, the Women's Cancer Program at UPMC Magee-Womens Hospital in Pittsburgh, Pennsylvania, was conducted. This study was approved by the institutional review board of the University of Pittsburgh. Potential study participants were recruited during their regular (usually every three weeks or once a month) clinic visits. Women with metastatic breast cancer were identified before their clinic visit, and a packet containing information about the project and study questionnaires was attached to the forms handed to all patients on admission to the clinic (e.g., forms concerning insurance verification, symptom assessment, and privacy). On patient entry to the clinic, the receptionist handed the forms and study packet to the patients; the patients were asked to read the information and, if they were interested in participating in the study, to complete the questionnaires. Potential participants could opt out of the study by returning the questionnaires to the staff without completing them. Participants completed the questionnaires independently in the waiting room and placed the completed questionnaires in a designated box to preserve anonymity. A student researcher collected the questionnaires and entered the data. Data entry was double verified.

Instruments

Study participants completed several different questionnaires. Nonvalidated instruments were used to collect demographic information and qualitative financial distress and management information. Demographic characteristics (marital status, race, gross household income and household size, level of education, age, employment status, insurance) were collected using a version of the University of Pittsburgh School of Nursing's demographic form. In addition, a short questionnaire containing open-ended questions was used to collect information regarding costs of metastatic breast cancer care and strategies for coping with healthcare-related costs.

Income level was determined using self-reported data on gross household income level and household size. Low-level income was defined as an annual income of less than 150% of the family income level as determined by federal poverty guidelines (U.S. Department of Education, 2017).

Financial toxicity was evaluated using the 11-item COST tool (de Souza et al., 2017). This measure assesses financial toxicity in patients with cancer; some items are reverse-scored. Lower values indicate worse financial toxicity. There is no cutoff score

established for this instrument. This instrument demonstrates high internal consistency (Cronbach alpha = 0.92) and has an intraclass correlation coefficient of 0.8 (95% confidence interval [0.57, 0.92]) for test-retest reliability. The Pearson correlation between the COST measurement and the Brief Profile of Mood States (a measure assessing psychological distress) was 0.26 ($p < 0.001$), indicating that higher financial distress was associated with worse psychological distress (de Souza et al., 2017).

The Functional Assessment of Cancer Therapy–Breast (FACT-B), version 4.0, evaluates quality of life in five subscales: physical well-being (7 items), social/family well-being (7 items), emotional well-being (6 items), functional well-being (7 items), and additional concerns (10 items; these are specific to breast cancer). Response scores on negatively phrased questions were reversed. Subscale scores were calculated by summing item responses. The total score was obtained by summing the individual subscale scores. If questions were skipped, scores were prorated using the average of the other answers in the scale when appropriate. Higher scores for the overall scale and subscales indicate better quality of life (Brady et al., 1997; Webster, Cella, & Yost, 2003). Psychometrics are well established for this instrument (Brady et al., 1997). Total score alpha coefficients were 0.9 for the FACT-B and the FACT-G, which is a general measure. Test-retest correlation coefficients were 0.85 for the FACT-B total score (Brady et al., 1997).

The NCCN Distress Thermometer measures cancer-related distress using a visual analog scale ranging from 0 (no distress) to 10 (great distress); it is frequently used in outpatient cancer settings (Holland & Bultz, 2007). There is moderate convergent validity ($r = 0.61$, $p = 0.001$) between the Distress Thermometer and other validated measures of global cancer-related distress (Holland & Bultz, 2007). A score of 4 has been determined to be the cutoff score for moderate distress and the trigger for psychological assistance referral (Holland & Bultz, 2007).

Differences between groups (low-level income versus high-level income study participants) were evaluated using *t* tests for continuous variables and chi-square tests or Fisher's exact tests for categorical variables, as appropriate. The Pearson correlation coefficient was used to assess the relationship among the COST, FACT-B, and Distress Thermometer instruments. A *p* value of less than 0.05 was considered significant. All analyses were performed using SAS, version 9.3.

Results

A total of 210 women with metastatic breast cancer were approached and received a study packet from the staff. Of these, 145 women (69% response rate) agreed to participate by completing and returning the questionnaires. Study participant characteristics are presented in Table 1. Study participants had a mean age of 58.1 years (SD = 12.5), all were female, and the majority were White (89%), partnered (60%), diagnosed with breast cancer less than 10 years ago, and receiving therapy. Overall, 143 participants reported having medical insurance, which was mostly private (the remaining two participants did not respond). Of the 145 study participants, 134 provided information on household income (based on gross annual household income and household size) and size; 36 (28%) had low-level income (\bar{X} age of 57.5 years [SD = 10.9]), and 92 (72%) had high-level income (\bar{X} age of 58 years [SD = 11.8]).

Participants with low-level income were more often Black, not partnered, and not employed compared to those with high-level income. Among participants with low-level income, 17 (49%) had government, Medicaid, or workers' compensation medical insurance, and 5 (14%) had private insurance. Many of the participants with low-level income had a household income that did not meet basic needs, experienced difficulty paying for basic needs, and had fewer years of formal education. Overall, participants had a median of 14 years of formal education (range = 2–28 years), whereas those with low-level income had a median of 12 years (range = 2–20) and those with high-level income had a median of 16 years (range = 4–28).

Financial Toxicity and Quality of Life

In the overall study population, the mean COST value (N = 138) was 22.6 (SD = 11.5, median = 23, range = 0–44), the mean total FACT-B score (N = 135) was 99 (SD = 22.9, median = 102, range = 36–140), and the mean Distress Thermometer score (N = 141) was 4.5 (SD = 2.9, median = 5, range = 0–10).

Compared to the high-level income group (N = 90), the low-level income group (N = 34) had significantly lower mean COST values (high-level income group: \bar{X} = 25.2, SD = 11.4, median = 27, range = 1–44; low-level income group: \bar{X} = 15.1, SD = 9.9, median = 12.6, range = 0–40). Total FACT-B scores were also lower among the low-level income group (N = 32) compared to the high-level income group (N = 89) (low-level income group: \bar{X} = 88.9, SD = 26.4, median = 85.6, range = 36–128.7; high-level income group: \bar{X} = 100.9, SD = 20.6, median = 103, range = 47–137).

Regarding the FACT-B, mean scores were significantly lower among members of the low-level income group for all subscales except emotional well-being and additional concerns. No significant differences between the low- and high-level income groups were observed for Distress Thermometer scores.

The Pearson correlation coefficient for the COST value and the total FACT-B score was 0.56 ($p < 0.0001$), indicating that worse financial toxicity was associated with worse quality of life. The subscales were individually moderately correlated with the COST value (Pearson correlation coefficient ranging from 0.39–0.5). The COST value was inversely correlated with the Distress Thermometer score (Pearson correlation coefficient of -0.43 , $p < 0.0001$).

Financial Distress and Resources

The investigator-created questionnaire included open-ended questions regarding the patient's experience with financial issues and worries, as well as the cause of financial issues and resources needed to help with financial issues. The majority of study participants (70 of 130), regardless of income level, attributed their financial distress to their illness. Personal finances, such as savings and retirement plans, were the financial resources most often used to assist with financial obligations of illness. Other financial resources used were assistance from family, insurance, basic needs assistance (e.g., food stamps), loans and donations, and transportation cost reimbursements. Requested resources included financial and psychological counseling and advice, higher income, financial assistance with basic needs, free parking and transportation, and an organized and centralized billing system.

Discussion

To better understand the relationships among financial toxicity, quality of life, and overall cancer-related distress among women with metastatic breast cancer, this study conducted a cross-sectional survey measuring financial toxicity, quality of life, cancer-related distress, and specific stressors and financial coping mechanisms among women with metastatic breast cancer.

This study suggests that, although the sample was largely insured, financial toxicity is experienced by most women with metastatic breast cancer and is exacerbated by low-level income status. The chronicity of the costs was illustrated with women attending a mean of 17 clinic visits annually and paying almost \$1,200 out of pocket each year for medical oncology access; these reported

TABLE 1. Sample Characteristics, Overall and by Income Level

| Characteristic | Overall (N = 145) | | Low-Level Income (N = 36) | | High-Level Income (N = 92) | | p ^a |
|---|----------------------|----|------------------------------|----|-------------------------------|----|----------------|
| | n | % | n | % | n | % | |
| Annual household income (\$) | | | | | | | < 0.05 |
| Less than 30,000 | 45 | 34 | 35 | 97 | 8 | 9 | - |
| 30,000-50,000 | 20 | 15 | 1 | 3 | 17 | 19 | - |
| Greater than 50,000 | 69 | 52 | - | - | 67 | 73 | - |
| Missing data | 11 | - | - | - | - | - | - |
| Difficulty paying for basic needs | | | | | | | < 0.05 |
| Not at all difficult | 79 | 57 | 7 | 20 | 64 | 70 | - |
| Somewhat difficult | 49 | 35 | 20 | 57 | 24 | 26 | - |
| Extremely difficult | 11 | 8 | 8 | 23 | 3 | 3 | - |
| Missing data | 6 | - | 1 | - | 1 | - | - |
| Employment status | | | | | | | < 0.05 |
| Full-time (greater than 35 hours per week) | 40 | 28 | 4 | 11 | 31 | 34 | - |
| Part-time (less than 35 hours per week) | 12 | 8 | 2 | 6 | 9 | 10 | - |
| Unemployed | 83 | 57 | 27 | 75 | 45 | 49 | - |
| Other | 10 | 7 | 3 | 8 | 7 | 8 | - |
| Household income meets basic needs | | | | | | | < 0.05 |
| Yes | 111 | 80 | 16 | 47 | 82 | 89 | - |
| No | 29 | 21 | 18 | 53 | 10 | 11 | - |
| Missing data | 5 | - | 2 | - | - | - | - |
| Importance of religion or spirituality | | | | | | | 0.28 |
| Not at all important | 9 | 7 | 1 | 3 | 8 | 9 | - |
| Somewhat important | 44 | 32 | 14 | 40 | 25 | 28 | - |
| Extremely important | 86 | 62 | 20 | 57 | 56 | 63 | - |
| Missing data | 6 | - | 1 | - | 3 | - | - |
| Marital status | | | | | | | < 0.05 |
| Married/living with partner | 86 | 60 | 8 | 22 | 69 | 75 | - |
| Not married/not living with partner | 58 | 40 | 28 | 78 | 23 | 25 | - |
| Missing data | 1 | - | - | - | - | - | - |
| Race | | | | | | | < 0.05 |
| White | 125 | 89 | 24 | 71 | 86 | 95 | - |
| Black | 7 | 5 | 6 | 18 | 1 | 1 | - |
| Other | 8 | 6 | 4 | 12 | 4 | 4 | - |
| Missing data | 5 | - | 2 | - | 1 | - | - |
| Type of medical insurance^b | | | | | | | |
| Medicare | 55 | 39 | 18 | 51 | 31 | 34 | 0.09 |
| Government/Medicaid/workers' compensation | 27 | 19 | 17 | 49 | 9 | 10 | < 0.05 |
| Private | 69 | 48 | 5 | 14 | 57 | 62 | < 0.05 |
| Other | 40 | 28 | 11 | 31 | 25 | 27 | 0.7 |
| Missing data | 2 | - | 1 | - | - | - | - |

^a Low-level versus high-level income were compared using chi-square test or Fisher's exact test for categorical variables and t test for continuous variables.

^b Participants could select more than one type of medical insurance.

Note. Because of rounding, percentages may not total 100.

costs do not include the much higher costs of co-payments, prescribed medications, and lost work time.

This study also found that worse financial toxicity was associated with worse quality of life among women with metastatic breast cancer. The discovery of this relationship is consistent with the broader financial toxicity in cancer care literature (de Souza & Yap, 2014; Meneses, Azuero, Hassey, McNees, & Pisu, 2012; Zafar et al., 2015). Spencer et al. (2017) reported on the change in health-related quality of life (5 months to 25 months postdiagnosis) among women with breast cancer in those who had and did not have financial toxicity. They noted that individuals with financial toxicity experienced worse quality of life at baseline with less improvement over time versus those who did not report financial toxicity (Spencer et al., 2017). The connection between financial toxicity and quality of life may be attributable to the significant influence of financial toxicity on patient and family decisions related to reduced spending on leisure activities (e.g., vacations) and basic items (e.g., groceries), reductions in savings, longer work hours, and inability to return to work (Meneses et al., 2012; Zafar et al., 2015). The clinical staff's ability to assess, identify, and intervene with patients regarding the financial toxicity of cancer care could potentially affect patient quality of life in the short and long term.

In 2015, the American Society of Clinical Oncology proposed a cost of cancer care framework that evaluates cancer treatments using three values: clinical benefit (efficacy), toxicity (safety), and cost (efficiency) (Schnipper et al., 2015). Instead of focusing solely on the efficacy of cancer treatment, the framework theoretically empowers patients by integrating the cost and financial impact of cancer care into considerations of quality of life, convenience, life circumstances, lifestyle, and personal finances (Schnipper et al., 2015). This personalized approach is particularly compelling for women with metastatic breast cancer because of the myriad of subtype-specific treatment options available to most women with metastatic breast cancer as they progress through the disease trajectory.

Implications for Nursing

Such a personalized approach to care likely would not be accomplished solely by the medical oncologist in today's busy clinical environment. The implementation of a financial counselor working with patients and families has been trialed in some clinical cancer care environments with promising results (Shankaran et al., 2017). Similarly, the oncology nurse or oncology nurse navigator may also be uniquely situated to assess

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- Integrating the cost and financial impact of cancer care into considerations of quality of life, convenience, life circumstances, lifestyle, and personal finances is an important consideration for nurses.
 - Women with metastatic breast cancer should be evaluated at the diagnosis of metastatic disease for their unique risk of financial toxicity.
 - Oncology nurses or oncology nurse navigators, together with financial counselors and medical oncologists, could work to assess financial distress and provide appropriate counseling and resources.
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financial distress; this role involves holistic patient assessment, as well as knowledge of cancer and its treatment and potential financial resources. The oncologist, oncology nurse and/or oncology nurse navigator, and financial counselor could work in tandem to assess the patient and his or her family for financial distress and then provide suitable counseling in accordance with appropriate treatment options (Pirl et al., 2014).

Women with metastatic breast cancer should be evaluated at the diagnosis of metastatic disease for their unique risk of financial toxicity. Results from the current study and previous research indicate that the assessment should include income status classified into low income or non-low income, with immediate financial assessment and intervention integrated into care (Gallups et al., 2017). Although the sample in the current study was not diverse enough to analyze women of a minority race, the social determinants of health, found by de Souza et al. (2017) to hold predictive value for financial distress in advanced cancer, could also be integrated into metastatic breast cancer care assessment for financial toxicity. Future research will need to examine the validity of these results with a larger and more diverse population of women with metastatic breast cancer, including a greater number of underinsured and uninsured patients. Examining this study's results among studies involving patients with other types of cancer will also be an important next step in investigating the impact of financial toxicity on cancer care outcomes.

Many breast cancer charities and resources are available within individual communities. Institutions treating women with metastatic breast cancer should examine their parking assistance, co-payment requirements, and overall cost of service because of the unique and chronic nature of metastatic breast cancer treatment. Community breast cancer charities

could also evaluate programming to ensure that support is provided across the trajectory of breast cancer illness and not exclusively to women diagnosed with early-stage cancer.

Clinicians who remain income neutral in their treatment decisions because of fear of treatment decision bias can no longer afford this luxury (Riaz, Bal, & Wise-Draper, 2016). They must consider the unique challenges that low-level income status brings to chronic progressive diseases, such as metastatic breast cancer, with a sensitivity toward out-of-pocket medication costs, resource availability, cost versus efficacy of suggested treatments, and assumed debt of the surviving family for low-quality treatments.

Conclusion

Financial toxicity is an established toxicity in cancer care. Metastatic breast cancer represents a unique paradigm in cancer care, with years of chronic therapy during a progressive, life-ending illness. This chronicity in illness and treatment can make patients more vulnerable to financial toxicity. This analysis of a cohort of 145 women with metastatic breast cancer indicated that financial toxicity is common among this cohort, more severe among low-level income women, and associated with worse quality of life and cancer-related distress.

To mitigate distress associated with financial toxicity, oncology nurses working with women with metastatic breast cancer should be aware of the potential for financial toxicity and work within their clinical settings to implement proactive assessment for appropriate referral.

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QUESTION GUIDE FOR A JOURNAL CLUB

Journal clubs can help to increase and translate findings to clinical practice, education, administration, and research. Use the following questions to start discussion at your next journal club meeting. Then, take time to recap the discussion and make plans to proceed with suggested strategies.

1. How comfortable are you discussing financial issues with patients?
2. What would make you more comfortable talking about this?
3. What has been your experience of working with a financial counselor in your institution?
4. How aware are you of resources to assist patients with financial difficulties?
5. How would you go about assessing patients for financial difficulties?

Visit <http://bit.ly/1vUqbVj> for details on creating and participating in a journal club. Contact pubONF@ons.org for assistance or feedback. Photocopying of the article for discussion purposes is permitted.

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