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Financial Toxicity in Adults With Cancer: Adverse Outcomes and Noncompliance

Thomas G. Knight, Allison M. Deal, Stacie B. Dusetzina, Hyman B. Muss, Seul Ki Choi, Jeannette T. Bensen, and Grant R. Williams

QUESTIONS ASKED: What is the prevalence of financial toxicity and its impact on subsequent health services? What potential areas of financial toxicity can be targeted for intervention?

SUMMARY ANSWER: Of 1,988 participants, 524 (26%) reported difficulty affording medical care. Patients who were identified as reporting financial toxicity were less likely to fill their medications, attend office visits, and to undergo recommended medical tests. The most commonly reported reasons for delayed medical care were not having insurance coverage and being unable to afford household expenses.

WHAT WE DID: Over 5 years, all patients presenting to a variety of University of North Carolina Health Care Oncology outpatient clinics were approached for participation in a survey. Within 2 weeks of enrollment, interviews were conducted by trained staff using a computer-assisted telephone interview. The interview included numerous structured and validated questionnaires with topics ranging from medical and social histories to cancer-specific health assessments, including barriers to care. Our primary outcome was patient-reported financial toxicity using Patient Satisfaction Questionnaire-18 question: "Do you have to pay for more medical care than you can afford?"

WHAT WE FOUND: Patients reporting financial toxicity were more likely to be \leq 65 years of age, female, nonwhite, non-English speaking, not married, less educated, and to have received a diagnosis more recently. Participants with financial toxicity were more likely to report noncompliance with medication owing to inability to afford prescription

drugs and to report forgoing mental health care, doctor's visits, and medical tests because of cost. Multiple reasons were identified for delayed care, including not having transportation, inability to pay their general household expenses, inability to pay for travel, and an inability to take time off of work.

We found that despite only using a single screening question as our identifier, we were able to identify an extremely high-risk population who reported financial toxicity that was associated with an increased risk for medical noncompliance with all aspects of medical care, including medications and doctor's visits. We were also able to find several specific areas that could be targets for intervention in this population, including transportation costs, work concerns, and insurance issues that potentially lead to delays in care.

BIAS, CONFOUNDING FACTOR(S): This was a single-center, cross-sectional study. As such, we could not specifically determine causal relationships between reported financial toxicity and noncompliance or delays in care. We also recognize because data are from a patient-reported survey, noncompliance outcomes were subject to recall bias. Finally, there is the question of applicability of our findings from a single center to other centers' practice.

REAL-LIFE IMPLICATIONS: Short-form screening for financial toxicity in patients with cancer identifies an extremely vulnerable population with an increased risk of noncompliance to all aspects of their medical care. This can potentially allow for routine screening and intervention in busy practices, which could affect morbidity and mortality rates. Additional study is needed of this pressing issue.

Financial Toxicity in Adults With Cancer: Adverse Outcomes and Noncompliance

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Abstract

Purpose

Because of the escalating cost of cancer care coupled with high insurance deductibles, premiums, and uninsured populations, patients with cancer are affected by treatment-related financial harm, known as financial toxicity. The purpose of this study was to describe individuals reporting financial toxicity and to identify rates of and reasons for affordability-related treatment noncompliance.

Methods

From May 2010 to November 2015, adult patients (age \geq 18 years) with cancer were identified from a Health Registry/Cancer Survivorship Cohort. Financial toxicity was defined as agreement with the phrase "You have to pay for more medical care than you can afford" from the Patient Satisfaction Questionnaire-18. Logistic regression and Fisher exact tests were used to compare groups.

Results

Of 1,988 participants, 524 (26%) reported financial toxicity. Patients reporting financial toxicity were more likely age 65 years or younger, female, nonwhite, non-English speaking, not married, less educated, and to have received a diagnosis more recently (all P < .001). Participants with financial toxicity were more likely to report noncompliance with medication, owing to inability to afford prescription drugs (relative risk [RR], 3.55; 95% CI, 2.53 to 4.98), and reported forgoing mental health care (RR, 3.89; 95% CI, 2.04 to 7.45), doctor's visits (RR, 2.98; 95% CI, 1.97 to 4.51), and medical tests (RR, 2.54; 95% CI, 1.49 to 4.34). The most endorsed reasons for delayed care were not having insurance coverage and being unable to afford household expenses.

Conclusion

More than 25% of adults with cancer reported financial toxicity that was associated with an increased risk for medical noncompliance. Financial toxicity remains a major issue in cancer care, and efforts are needed to ensure patients experiencing high levels of financial toxicity are able to access recommended care.

INTRODUCTION

Treatment for cancer in the United States has increasingly become specialized and expensive, with increased focus on targeted and personalized therapies. Studies have documented average launch prices for

anticancer drugs increased by 10% annually, or an average of \$8,500 per year, from 1995 to 2013,^{2,3} after accounting for inflation and health benefits. At the same time, national surveys revealed that retail prescription medicine expenditures for

DOI: https://doi.org/10.1200/JOP. 18.00120; published online ahead of print at jop.ascopubs.org on October 24, 2018. cancer treatment increased five-fold between these years, from \$2.0 billion in 2001 to \$10.0 billion in 2011.⁴ These high medication costs are worrisome because they result in high out-of-pocket spending requirements for patients needing treatments, which, in turn, are often related to poorer adherence to medication therapies.⁵⁻¹⁰ However, increasing medication costs, although important, are just one of many contributors to the financial burden for patients with cancer, which is now referred to as financial toxicity.¹¹⁻¹³ There is a growing national consensus on the importance of defining and finding interventions to ameliorate financial toxicity.¹⁴

Previous research in this area focused on identifying and characterizing the extent to which patients report financial distress or toxicity. These analyses include several small-scale pilot studies that used patient-reported data to quantify experiences with financial toxicity^{11,15-18} and multiple studies that used large national databases focused on identifying the role of patient out-of-pocket costs on outcomes.^{6,12,19-21} In this study, we used patient reported information from a large academic medical system in the southeastern United States to evaluate the prevalence of self-reported financial toxicity, the impact of financial toxicity on subsequent health services, and to identify potential areas of financial toxicity that could be targeted for intervention.

METHODS

We conducted a retrospective, cross-sectional analysis of data collected for a large hospital-based observational cancer cohort. The University of North Carolina (UNC) at Chapel Hill Health Registry/Cancer Survivorship Cohort is an institutional review board-approved (No. 09-0605) incident/prevalent cohort of patients with cancer that integrates a comprehensive database of clinical, epidemiologic, and interview data with repositories of biologic specimens and tumor tissue. Participants were recruited by research assistants embedded into a variety of UNC Health Care oncology outpatient clinics at the North Carolina Cancer Hospital with the following eligibility criteria: age ≥ 18 years, North Carolina mailing address, and English or Spanish language proficiency. All patients meeting these criteria in these clinics were approached by research staff, and 52% of approached individuals were successfully enrolled. Participants who were unable to provide informed consent or participate in interview questionnaires were excluded. Patients were enrolled in the Health Registry between May 2010 and October 2015, and these patients completed baseline questionnaires between January 2011 and November 2015. For inclusion in our analysis, we restricted data to those from participants \geq 18 years old who had a recorded cancer diagnosis and had completed the survey \geq 90 days from their diagnosis. We chose this time frame to theoretically capture participants who had already been receiving bills for their treatment and were able to gauge the impact of these bills on their life.

Within 2 weeks of enrollment, interviews were conducted by trained staff using a computer-assisted telephone interview. The interview included numerous structured and validated questionnaires with topics ranging from medical and social histories to cancer-specific health assessments, including barriers to care. The focus of our analyses was the Patient Satisfaction Questionnaire (PSQ-18). The PSQ-18 is an 18item scale created for patients to evaluate their doctor; it specifically measures general satisfaction, technical quality, interpersonal manner, communication, financial aspects, time spent with doctor, and accessibility and convenience. 22,23 It has also been previously used in the assessment of financial toxicity.²⁴ Our analyses also included in the Functional Assessment of Cancer Therapy–General Population (FACT-GP) and an internally developed access to health care questionnaire. The FACT-GP, version 4, is a 21-item scale that measures health-related quality of life using four subscales: physical, functional, emotional, and social well-being.²⁵ The access to health care questionnaire used in this study has not been validated but was constructed using questions adapted from existing validated questionnaires in addition to questions developed by the Health Registry team (Data Supplement).

In addition to survey responses, demographics (eg, age, race) were confirmed with the patient and clinical information was obtained from the UNC Health Care medical record, including cancer diagnosis and stage. Of note, there were only data available in the UNC Health record, because we did not have access to nonaffiliated practices or hospitals. Data received for this project were linked using an honest broker model (the independent UNC Health Registry serving as the honest broker with a de-identified analytic file containing the medical record, demographic, and survey data were provided to the investigators for this analysis).

Our primary outcome was patient-reported financial toxicity using the PSQ-18 statement: "You have to pay for more medical care than you can afford." In the questionnaire, participants were asked to respond to this statement in one of five categories (strongly agree, agree, uncertain, disagree, and strongly disagree). Participants were dichotomized as

exhibiting financial toxicity (strongly agree or agree) or not exhibiting financial toxicity (all other responses).

Descriptive statistics were used to describe the baseline characteristics of the sample. Patients' characteristics between the two groups (ie, financial toxicity or not exhibiting financial toxicity) were evaluated using t test for continuous variables and the χ^2 test for categorical variables. Adjusted risk ratios and 95% CIs for the association between patient clinical and sociodemographic characteristics and the presence of subjective financial toxicity were estimated using Poisson regression with a robust variance estimate. Variables were selected for inclusion in multivariable models, using a combination of clinical relevance and statistical selection criterion in unadjusted analyses (P < .10). All analyses were completed using SAS, version 9.3 (SAS Institute, Cary, NC).

RESULTS

Table 1 lists the study demographics. The study cohort consisted of 1,988 participants. The mean age was 59 (standard deviation, 12.3) years, 62% were women, 81% were white, and 16% were black. The most common tumor types were breast (31%), GI (23%), and genitourinary (17%; Table 1). Most participants reported educational attainment of less than a college degree (55%) and were not currently working for pay (60%). More than half of the participants (56%) had received a cancer diagnosis within 2 years of their participation in the survey.

Of the 1,988 participants, 524 respondents (26%) agreed or strongly agreed that they had to pay more for medical care than they could afford. In a univariable comparison of those who did and did not report financial toxicity, the patients who reported financial toxicity were more likely be \leq 65 years of age (82% v 62%) and nonwhite (30% v 16%). They were also more likely to be unmarried (42% v 28%) and possess less education than a college degree (68% v 50%; all P < .001). The group reporting financial toxicity were also more likely to have received a cancer diagnosis within the last 3 years (73% v 66%, P < .001) as opposed to \geq 3 years from the time of the survey. Finally, as measured by the FACT-GP, patients reporting financial toxicity also had significantly lower physical, functional, emotional, and social well-being compared with those patients without financial toxicity (all P < .001).

Table 2 lists the adjusted relative risks (RRs) for reporting financial toxicity. In an adjusted model that included all covariables, some risk factors identified as statistically significant independent predictors of financial toxicity were

lower education levels (RR, 2.41; 95% CI, 1.59 to 3.65 for not having a high school diploma), being unmarried (RR, 1.35; 95% CI, 1.13 to 1.62), and being of black race (RR, 1.63; 95% CI, 1.34 to 1.99). Protective factors included age > 65 years (RR, 0.41; 95% CI, 0.36 to 0.66) and being longer than 3 years from diagnosis (RR, 0.78; 95% CI, 0.63 to 0.97). Cancer type was not significant on adjusted analysis.

The cohort of patients meeting the criteria for financial toxicity was also more likely to report noncompliance in key areas of treatment, because of an inability to afford their medical care over the past year (Table 3). This was true even when we adjusted for age, race, education, and days from diagnosis to baseline survey. Specifically, in this model, participants reporting financial toxicity were more likely to report needing but being unable to afford prescription (RR, 3.55; 95% CI, 2.53 to 4.98) and over-the-counter (RR, 2.24; 95% CI, 1.40 to 3.59) medications. They also reported noncompliance because of cost concerns of other key components of medical care, such as doctor's visits (RR, 2.98; 95% CI, 1.97 to 4.51), medical tests (RR, 2.54; 95% CI, 1.49 to 4.34), mental health care (RR, 3.89; 95% CI, 2.04 to 7.45), and dental visits (RR, 2.86; 95% CI, 2.20 to 3.73).

Finally, participants were asked if they had delays getting care in the year before the survey and the reasons leading to this delay. Multiple reasons were identified for delayed care, which were found to be more prevalent in patients reporting financial toxicity even when adjusted for age, race, education, and days from diagnosis to baseline survey. These reasons included not having transportation (RR, 1.82; 95% CI, 1.04 to 3.20), lack of insurance (RR, 1.92; 95% CI, 1.33 to 2.76), inability to pay their general household expenses (RR, 2.73; 95% CI, 2.01 to 3.70), inability to pay for travel (RR, 2.32; 95% CI, 1.40 to 3.86), and an inability to take time off of work (RR, 2.72; 95% CI, 1.67 to 4.42; all P < .05).

DISCUSSION

Over the past several years, the impact of cancer and its treatment on patient financial well-being has become a topic of major concern. We undertook this analysis to better understand the prevalence and consequences of financial toxicity in adults with cancer as well as to identify potential areas amendable to intervention. In a large academic medical center in the southeastern United States, we found that 26% of patients visiting oncology clinics reported having to pay for more medical care than they could afford. Patients who were identified as reporting financial toxicity were less likely to fill

Table 1. Patient Characteristics

Characteristic	Overall (N = 1,988)	No Financial Toxicity (n = 1,464)	Financial Toxicity (n = 524)	P
Age, years < 50 50-65 > 65	397 (20.0) 943 (47.4) 648 (32.6)	259 (17.7) 650 (44.4) 555 (37.9)	138 (26.3) 293 (55.9) 93 (17.7)	< .001
Sex Female Male	1238 (62.3) 750 (37.7)	900 (61.5) 564 (38.5)	338 (64.5) 186 (35.5)	.2197
Race White Black Other	1585 (80.5) 319 (16.2) 64 (3.3)	1219 (84.2) 185 (12.8) 43 (3.0)	366 (70.2) 134 (25.7) 21 (4.0)	< .001
Cancer type Breast GI Gynecologic Genitourinary Other	612 (30.8) 449 (22.6) 138 (6.9) 333 (16.8) 456 (22.9)	453 (30.9) 307 (21.0) 99 (6.8) 254 (17.3) 351 (24.0)	159 (30.3) 142 (27.1) 39 (7.4) 79 (15.1) 105 (20.0)	.0325
Stage (n = 673 missing data) 0 1 2 3	98 (7.5) 430 (32.7) 340 (25.9) 279 (21.2) 168 (12.8)	76 (7.8) 339 (34.9) 231 (23.8) 200 (20.6) 125 (12.9)	22 (6.4) 91 (26.5) 109 (31.7) 79 (23.0) 43 (12.5)	.0109
Time since diagnosis 90 days to 1 year 1-2 years 2-3 years > 3 years	686 (34.5) 418 (21.0) 244 (12.3) 640 (32.2)	479 (32.7) 305 (20.8) 183 (12.5) 497 (33.9)	207 (39.5) 113 (21.6) 61 (11.6) 143 (27.3)	.0129
Marriage status Not married Married	622 (31.6) 1345 (68.4)	403 (27.8) 1046 (72.2)	219 (42.3) 299 (57.7)	< .001
Education Some high school or less High school graduate or GED certificate Some college or technical school College graduate (bachelor's degree) Postgraduate or professional degree	121 (6.2) 414 (21.1) 536 (27.3) 480 (24.4) 414 (21.1)	75 (5.2) 266 (18.4) 375 (26.0) 377 (26.1) 352 (24.4)	46 (8.8) 148 (28.5) 161 (31.0) 103 (19.8) 62 (11.9)	< .001
Work for pay No Yes	1191 (60.0) 795 (40.0)	898 (61.4) 564 (38.6)	293 (55.9) 231 (44.1)	.0273
FACT-GP score, mean (SD) Physical well-being Functional well-being Emotional well-being Social well-being	22.68 (5.32) 19.31 (6.86) 19.55 (4.81) 21.16 (5.90)	23.21 (5.01) 20.00 (6.50) 19.82 (4.74) 21.64 (5.71)	21.17 (5.84) 17.35 (7.46) 18.81 (4.95) 19.80 (6.24)	< .001 < .001 < .001 < .001

NOTE. Data given as No. (%) unless otherwise indicated.

Abbreviations: FACT-GP, Functional Assessment of Cancer Therapy—General Population; GED, General Educational Development; SD, standard deviation.

Table 2. Unadjusted and Adjusted Relative Risk of Financial Toxicity

	Unadjusted Poisson Re	Unadjusted Poisson Regression		Adjusted Poisson Regression*		
Variable	Relative Risk (95% CI)	P	Relative Risk (95% CI)	P		
Age, years < 50 50-65 > 65	1.00 0.89 (0.76 to 1.05) 0.41 (0.33 to 0.52)	 .182 < .001	1.00 0.89 (0.73 to 1.09) 0.49 (0.36 to 0.66)	 .270 < .001		
Race White Black Other	1.00 1.82 (1.55 to 2.13) 1.42 (0.99 to 2.04)	 < .001 .057	1.00 1.63 (1.34 to 1.99) 0.84 (0.46 to 1.52)	 < .001 .565		
Cancer type Breast GI Gynecologic Genitourinary Other	1.00 1.22 (1.01 to 1.47) 1.09 (0.81 to 1.46) 0.91 (0.72 to 1.15) 0.89 (0.72 to 1.10)		1.00 1.20 (0.95 to 1.52) 1.17 (0.82 to 1.66) 1.02 (0.75 to 1.40) 1.00 (0.75 to 1.32)	 .119 .391 .888 .974		
Stage 1 2 3 4 0	1.00 1.51 (1.19 to 1.92) 1.34 (1.03 to 1.74) 1.21 (0.88 to 1.66) 1.06 (0.70 to 1.60)	— .001 .029 .238 .778	1.00 1.36 (1.06 to 1.73) 1.24 (0.95 to 1.60) 1.06 (0.76 to 1.47) 1.07 (0.73 to 1.58)	 .014 .109 .730 .715		
Time from diagnosis to survey 90 days to 1 year 1-2 years 2-3 years > 3 years	1.00 0.90 (0.74 to 1.09) 0.83 (0.65 to 1.06) 0.74 (0.62 to 0.89)		1.00 0.77 (0.61 to 0.99) 0.79 (0.59 to 1.06) 0.78 (0.63 to 0.97)			
Marriage status Not married Married	1.58 (1.37 to 1.83) 1.00	< .001 —	1.35 (1.13 to 1.62) 1.00	.001		
Education Not beyond high school Beyond high school	1.59 (1.37 to 1.84) 1.00	< .001 —	1.43 (1.18 to 1.74) 1.00	< .001 —		
Work for pay Yes No	1.00 0.85 (0.73 to 0.98)	<u> </u>	1.00 0.97 (0.80 to 1.17)	<u> </u>		

Abbreviation: — not applicable.

their medications, attend office visits, and undergo recommended medical tests. The most commonly reported reasons for delayed medical care was difficulties with transportation, lack of insurance, inability to take time off work, inability to pay for travel, and inability to pay general household expenses.

Multiple definitions of financial toxicity exist. In this study, we focused on whether the patient agreed with the statement "You have to pay for more medical care than you can afford"

from the PSQ-18 to screen a large number of patients who were potentially experiencing financial toxicity. Asking this single question to screen and identify a population at high risk for financial toxicity could be valuable in in the context of a busy clinic environment. Despite only using a single screening question as our identifier, we were able to spotlight an extremely high-risk population consisting of > 25% of our participants who reported financial toxicity that was

^{*}Adjusted for all covariables listed in the table

Table 3. Noncompliance in Key Areas of Treatment

	Report Financial	Does Not Report		Unadjusted		Adjusted*	
Patient Issue	Toxicity (n = 524), % (No.)	Financial Toxicity (n = 1,464), % (No.)	P	Relative Risk (95% CI)	P	Relative Risk (95% CI)	P
Needed but unable to afford							
Prescription medication	17.7 (93)	3.7 (54)	< .001	4.80 (3.49 to 6.61)	< .001	3.55 (2.53 to 4.98)	< .001
Mental health care	5.7 (30)	1.1 (16)	< .001	5.23 (2.87 to 9.51)	< .001	3.89 (2.04 to 7.45)	< .001
Dental care	23.3 (122)	6.8 (99)	< .001	3.44 (2.69 to 4.39)	< .001	2.86 (2.20 to 3.73)	< .001
Doctor's visits	11.5 (60)	2.9 (42)	< .001	3.99 (2.72 to 5.84)	< .001	2.98 (1.97 to 4.51)	< .001
Medical tests	6.3 (33)	1.8 (26)	< .001	3.54 (2.14 to 5.87)	< .001	2.54 (1.49 to 4.34)	.0006
OTC medications	7.7 (40)	2.4 (35)	< .001	3.19 (2.05 to 4.97)	< .001	2.24 (1.40 to 3.59)	.0008
Reasons for delays in medical care							
Did not have transportation	5.4 (28)	2.1 (31)	< .001	2.52 (1.53 to 4.17)	< .001	1.82 (1.04 to 3.20)	.0363
Could not take time off work	7.6 (40)	1.9 (28)	< .001	3.99 (2.48 to 6.39)	< .001	2.72 (1.67 to 4.42)	< .001
Could not afford travel expenses	6.5 (34)	2.1 (31)	< .001	3.06 (1.90 to 4.93)	< .001	2.32 (1.40 to 3.86)	.0012
Did not have health insurance	10.7 (56)	3.8 (56)	< .001	2.79 (1.95 to 3.98)	< .001	1.92 (1.33 to 2.76)	< .001
Could not afford household expenses	17.9 (94)	4.9 (71)	< .001	3.69 (2.76 to 4.94)	< .001	2.73 (2.01 to 3.70)	< .001

Abbreviation: OTC, over the counter.

associated with an increased risk for medical noncompliance, including an inability to afford medications and doctor's visits. To that end, our calculated prevalence of 26% is actually lower than the 42% seen in the Zafar et al¹¹ pilot study, but is similar to the 29% in the Medical Expenditure Panel Survey data of patients with cancer reported by Kale et al,¹⁷ which encompassed a much larger population. Patients identified as reporting financial toxicity also had a demographic profile similar to that in other reports where being younger, nonwhite, less educated, and not married were associated with greater rates of financial toxicity. ^{15,20,27}

In terms of noncompliance, several studies have shown this is an issue in specific disease processes. Dusetzina et al⁶ found that patients with chronic myeloid leukemia and high copayments were at risk for nonadherence to tyrosine kinase inhibitor therapy, and Neugut et al²⁸ found that higher prescription copayments were associated with nonpersistence and nonadherence to aromatase inhibitor therapy. In our study, we also saw that patients who exhibited financial toxicity were much more likely to be unable to afford their prescription and over-the-counter medications. However, one of the key findings in our study is that this noncompliance with treatment extends to not only medications but also with all aspects of medical care. Of great concern is the increased rate of missed doctor's visits and medical tests that can have serious treatment consequences, particularly in oncologic care. It should also be noted that the majority of our patients

exhibiting financial toxicity were still within 2 years of their initial diagnosis and presumably some were under active treatment, which makes it imperative that they are closely monitored with frequent visits and laboratory tests. The noncompliance secondary to cost seen in this study is of grave concern for our patients and can lead to potentially significant morbidity and mortality.

In addition to identifying rates of noncompliance with recommended medical care, owing to financial concerns, we also hoped to identify potential targets for intervention for patients experiencing financial toxicity. Historically, oncologists have been reluctant to discuss costs of treatment with patients. In one survey, Schrag et al²⁹ found that 58% of medical oncologists reported discussing the cost of treatment with patients only sometimes or less because of a perceived inability to address the problem. This is possibly linked to a concern for strategy even if these issues are identified. However, we found several specific areas, including transportation costs, work concerns, and insurance issues, that potentially lead to delays in care. These are issues that, in a real-world clinic setting, are sometimes unable to be modified; however, they are also issues that potentially can be addressed with institutional and foundational support if identified and discussed with researchers heading pilot studies in this area, which are starting to be reported and that show feasibility.³⁰ In a recent study of 11,186 new patients with cancer seen by specially trained financial navigators, patient saved an average

^{*}Adjusted for education, age, race, and days from diagnosis to baseline survey.

of \$33,265 annually on medication, \$12,256 through enrollment in insurance plans, \$35,294 with premium assistance, and \$3,076 with copay assistance.³¹ In our practice, transportation needs are factored into overall treatments plans, with treatments and laboratory work being done as close to the patient's home as possible, when feasible, and funding made available for travel needs. More research is urgently needed and ongoing.

We should acknowledge key limitations of our study. This was a single-center, retrospective review of an institutional database. As such, we cannot specifically determine causal relationships between reported financial toxicity and noncompliance or delays in care. We also recognize that because the data were taken from a patient-reported survey, noncompliance outcomes were subject to recall bias. Another limitation is a lack of patients with lung cancer or hematologic malignancy in this database, which represented an enrollment bias as a result of the current enrollment structure, which was clinic based and did not have enrollment staff regularly at these clinics. We are also missing several key variables, owing to study design, including treatment information and additional sociodemographic data, including income and insurance, which limit our analysis. Also in terms of design, our definition of financial toxicity is somewhat broad by intention because we wanted to be able to quickly implement a one-question screener into a real-world intervention. In particular, the Comprehensive Score for Financial Toxicity measure has been subsequently developed as a validated tool to assess for financial toxicity.^{32,33} However, our data do seem consistent with t previously reported data and we feel there is real value to shorter screening tools in a busy clinical environment. 11,15-18 Finally, there is the question of applicability of our findings from a single center to other centers' practice. However, as a large, state-run hospital system, our patient population did seem to be quite diverse at both demographic and socioeconomic levels, which is reflected in Table 1. Nonetheless, with the similarity of our findings to those of smaller-scale research reported from different geographic areas, we do feel that we have been able to identify and characterize a problem that is systemic throughout the American health care system. Finally, we should acknowledge that our project encompasses the time before and after the implementation of the Affordable Care Act in the United States, with the important caveat that North Carolina did not participate in the Medicaid expansion, and this may have affected the results of our study.

Ultimately, the financial impact of cancer care is a relatively new area of research that is increasingly being recognized as a major factor in the outcomes of patients with cancer. We feel that our data confirm findings of smaller studies of patient-reported data, but also, and perhaps more importantly, enable us to identify with one question an extremely vulnerable population that could benefit from interventional strategies to address financial hardship, which would seem to indicate that there is validity in short-form screening in this issue. This will hopefully allow our group as well as investigators nationally to implement screening procedures with related and better-validated screening tools for patients in the clinic to identify those at highest risk and quickly address these issues.

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References

- ${\bf 1.}$ Kantarjian H, Rajkumar SV: Why are cancer drugs so expensive in the United States, and what are the solutions? Mayo Clin Proc 90:500-504, 2015
- 2. Howard DH, Bach PB, Berndt ER, et al: Pricing in the market for anticancer drugs. J Econ Perspect 29:139-162, 2015
- **3.** Dusetzina SB: Drug pricing trends for orally administered anticancer medications reimbursed by commercial health plans, 2000-2014. JAMA Oncol 2: 960-961. 2016
- **4.** Soni A: Trends in use and expenditures for cancer treatment among adults 18 and older, U.S. civilian noninstitutionalized population, 2001 and 2011. http://mepsahrqgov/data_files/publications/st443/stat443pdf.
- **5.** Piette JD, Heisler M, Wagner TH: Cost-related medication underuse among chronically ill adults: The treatments people forgo, how often, and who is at risk. Am J Public Health 94:1782-1787, 2004
- $\hbox{\bf 6.} \ {\rm Dusetzina} \ {\rm SB, Winn \ AN, \ Abel \ GA, \ et \ al: \ Cost \ sharing \ and \ adherence \ to \ tyrosine \ kinase \ inhibitors \ for \ patients \ with \ chronic \ myeloid \ leukemia. \ J \ Clin \ Oncol \ 32: \ 306-311, \ 2014$

- **7.** Streeter SB, Schwartzberg L, Husain N, et al: Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. J Oncol Pract 7:46s-51s, 2011 (3 Suppl)
- **8.** Kent EE, Forsythe LP, Yabroff KR, et al: Are survivors who report cancer-related financial problems more likely to forgo or delay medical care? Cancer 119: 3710-3717, 2013
- **9.** Weaver KE, Rowland JH, Bellizzi KM, et al: Forgoing medical care because of cost: Assessing disparities in healthcare access among cancer survivors living in the United States. Cancer 116:3493-3504, 2010
- **10.** Doshi JA, Li P, Huo H, et al: Association of patient out-of-pocket costs with prescription abandonment and delay in fills of novel oral anticancer agents. J Clin Oncol 36:476-482, 2018
- **11.** Zafar SY, Peppercorn JM, Schrag D, et al: The financial toxicity of cancer treatment: A pilot study assessing out-of-pocket expenses and the insured cancer patient's experience. Oncologist 18:381-390, 2013
- 12. Dusetzina SB, Basch E, Keating NL: For uninsured cancer patients, outpatient charges can be costly, putting treatments out of reach. Health Aff (Millwood) 34: 584-591, 2015
- 13. Bestvina CM, Zullig LL, Yousuf Zafar S: The implications of out-of-pocket cost of cancer treatment in the USA: A critical appraisal of the literature. Future Oncol 10: 2189-2199, 2014
- **14.** Zafar SY: Financial toxicity of cancer care: It's time to intervene. J Natl Cancer Inst 108:div370, 2015
- **15.** Zafar SY, McNeil RB, Thomas CM, et al: Population-based assessment of cancer survivors' financial burden and quality of life: A prospective cohort study. J Oncol Pract 11:145-150, 2015
- **16.** Stump TK, Eghan N, Egleston BL, et al: Cost concerns of patients with cancer. J Oncol Pract 9:251-257, 2013
- 17. Kale HP, Carroll NV: Self-reported financial burden of cancer care and its effect on physical and mental health-related quality of life among US cancer survivors. Cancer 122:283-289, 2016
- **18.** Bestvina CM, Zullig LL, Rushing C, et al: Patient-oncologist cost communication, financial distress, and medication adherence. J Oncol Pract 10:162-167, 2014
- **19.** Ramsey S, Blough D, Kirchhoff A, et al: Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. Health Aff (Millwood) 32:1143-1152, 2013

- **20.** Aizer AA, Falit B, Mendu ML, et al: Cancer-specific outcomes among young adults without health insurance. J Clin Oncol 32:2025-2030, 2014
- **21.** Walker GV, Grant SR, Guadagnolo BA, et al: Disparities in stage at diagnosis, treatment, and survival in nonelderly adult patients with cancer according to insurance status. J Clin Oncol 32:3118-3125, 2014
- **22.** Marshall GN: The Patient Satisfaction Questionnaire Short Form (PSQ-18). Santa Monica, CA: RAND Corporation, 1994
- **23.** Thayaparan AJ, Mahdi E: The Patient Satisfaction Questionnaire Short Form (PSQ-18) as an adaptable, reliable, and validated tool for use in various settings. Med Educ Online 18:21747. 2013
- **24.** Chino F, Peppercorn J, Taylor DH, Jr., et al: Self-reported financial burden and satisfaction with care among patients with cancer. Oncologist 19:414-420, 2014
- **25.** Cella DF, Tulsky DS, Gray G, et al: The Functional Assessment of Cancer Therapy scale: Development and validation of the general measure. J Clin Oncol 11:570-579, 1993
- **26.** Spiegelman D, Hertzmark E: Easy SAS calculations for risk or prevalence ratios and differences. Am J Epidemiol 162:199-200, 2005
- **27.** Shankaran V, Jolly S, Blough D, et al: Risk factors for financial hardship in patients receiving adjuvant chemotherapy for colon cancer: A population-based exploratory analysis. J Clin Oncol 30:1608-1614, 2012
- **28.** Neugut Al, Subar M, Wilde ET, et al: Association between prescription copayment amount and compliance with adjuvant hormonal therapy in women with early-stage breast cancer. J Clin Oncol 29:2534-2542, 2011
- **29.** Schrag D, Hanger M: Medical oncologists' views on communicating with patients about chemotherapy costs: A pilot survey. J Clin Oncol 25:233-237, 2007
- **30.** Shankaran V, Leahy T, Steelquist J, et al: Pilot feasibility study of an oncology financial navigation program. J Oncol Pract 14:e122-e129, 2018
- **31.** Yezefski T, Steelquist J, Watabayashi K, et al: Impact of trained oncology financial navigators on patient out-of-pocket spending. Am J Manag Care 24;S74-S79, 2018 (5 Suppl)
- **32.** de Souza JA, Yap BJ, Hlubocky FJ, et al: The development of a financial toxicity patient-reported outcome in cancer: The COST measure. Cancer 120:3245-3253, 2014
- **33.** de Souza JA, Yap BJ, Wroblewski K, et al: Measuring financial toxicity as a clinically relevant patient-reported outcome: The validation of the COmprehensive Score for financial Toxicity (COST). Cancer 123:476-484, 2017

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Financial Toxicity in Adults With Cancer: Adverse Outcomes and Noncompliance

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