


Re-Validation of the COMprehensive Score for Financial Toxicity (COST): Assessing the Scale's Utility in Chronic Disease Populations

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ABSTRACT

OBJECTIVE: To report the psychometric properties of the COMprehensive Score for financial Toxicity (COST) patient-reported outcome measure (PROM), an 11-item scale previously validated among patients diagnosed with cancer and receiving chemotherapy.

METHODS: Data come from a cross-sectional survey (n = 2755 response rate of 87%) of participants in a remote digital health coaching intervention collected between January 2017 and February 2019.

RESULTS: COST demonstrated very good internal consistency (*Cronbach's alpha* = .89) and good convergent validity. Lower financial toxicity was associated with improved physical and mental well-being HRQOL measures after controlling for covariates (*b* = 0.13, *P* < .0001; *b* = 0.28, *P* < .0001, respectively). Supplemental analyses indicated that the COST instrument loaded on 2 factors.

CONCLUSIONS: The COST measure of financial toxicity has good internal consistency and predictive validity in a sample of patients with chronic conditions. However, contrary to previous research examining the psychometric properties of COST in a sample of individuals with cancer, which found COST to be unidimensional, our analyses indicated that the COST measure of financial toxicity is multidimensional in a sample of individuals with chronic conditions. In particular, the items that asked about “general financial wellbeing” loaded on the second factor while “illness-related financial wellbeing” loaded on the first.

KEYWORDS: Financial toxicity, measurement, chronic disease, health-related quality of life (HRQOL)

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Highlights

What is already known about the topic?

- Financial toxicity is an important patient-reported outcome (PRO) associated with Health-Related Quality of Life (HRQOL) outcomes in individuals with a cancer diagnosis
- The COMprehensive Score for financial Toxicity (COST) is a validated measure of financial toxicity in individuals with a cancer diagnosis.

What insights does the paper provide for informing health-care-related decision making?

- The COST measure of financial toxicity is associated with measures of mental and physical HRQOL in a sample of individuals with chronic conditions.
- The COST measure of financial toxicity is a clinically relevant, PRO that can be used with a variety of chronic conditions.

The prevalence of chronic disease is increasing as the population ages and medical interventions extend lives that might otherwise have been cut short. Sixty-percent of Americans had at least 1 chronic condition in 2014 and multimorbidity is common: 42% had 2 or more conditions; and 29% had 3 or more chronic conditions, with the most common conditions being hypertension and lipid disorders.¹ Living with a chronic illness introduces new health management challenges and new forms of stress, and, frequently, causes individuals to miss work or take less remunerated positions to accommodate their disease.² Taken together, the medical expenses associated with having health issues and systematically earning lower wages place chronically ill individuals at a higher risk for experiencing financial hardships.³ The medical expenses and opportunity costs associated with chronic conditions may lead to “financial toxicity,” creating a barrier to successful chronic conditions management.

Financial toxicity is a term used to describe how poor health creates financial problems for patients. Financial toxicity is the product of both objective financial burdens due to the care costs, as well as, a patient's perceived financial distress.⁴ In



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addition to costs directly associated with care, it is common for people with chronic illnesses to have reduced income due to a limited ability to work, incur additional non-medical expenses, and draw upon other resources from friends and family for support.⁵ Therefore, assessing chronically ill patients' propensity for financial toxicity is an important patient-reported outcome (PRO) that needs to be managed.⁶

The measurement of financial toxicity has been associated with cancer care where treatments often cause patients to miss work and sustain large out-of-pocket-costs. Hence, there is a double impact from elevated medical expenses and declining income for both individuals and their families. To assess financial toxicity among cancer patients, the COmprehensive Score for financial Toxicity (COST) survey was developed.⁷ The scale has 11 items that are summed to assess the individual's financial stress level. As a PRO tool, the COST survey has been validated for use in cancer populations.⁸

The purpose of this study was to determine if the COST survey could be adapted for use with other patient populations. First, the survey was modified to be disease agnostic by changing the wording of 1 item to reflect the respondent's "condition" rather than "cancer." Next, the survey was administered to 2798 people with chronic conditions enrolled in a wellness coaching program. Finally, our team replicated the methods of de Souza et al⁸ to validate the instrument in cancer populations with participant responses.

Having a validated measure of financial toxicity for chronically ill patients is important for 3 audiences. For clinicians, having a clear picture of their patients' mental health, including stress induced by financial factors, is useful in caring for the whole person. Employers and insurance companies can use the information to design better interventions and products to meet the needs of chronically ill members. Lastly, patients themselves can use the COST results to quantify their own stress level, better cope with those stressors, and make future decisions.⁹

Materials and Methods

Sample

Data came from a survey of individuals who average 1 or more chronic diseases and were enrolled in a remote digital health coaching intervention delivered via PackHealth. PackHealth supports over 30 different chronic diseases, including cardio-metabolic, autoimmune, respiratory, cancer, mental health, and specialized or rare conditions. Patients could be enrolled with multiple diagnoses. Within the current study sample, respondents had the following diagnoses: cardiometabolic (n = 221); pain management (n = 195); pulmonary issues (n = 192) immunology (n = 192); oncology (n = 176); and other referrals (n = 185).

Participants enrolled in the health coaching intervention received a weekly call from their personal Health Advisor along with digital "nudges" via text messages and easy-to-understand education materials to improve the core health behaviors that drive outcomes including items such as nutrition, exercise, stress,

sleep, or financial toxicity. Due to the belief that financial toxicity is a foundational health issue, PackHealth began measuring financial toxicity among its program participants in January 2017 across all programs. Data were gathered during the first 2 weeks of enrollment prior to the delivery of the health coaching intervention. Participants enrolled in the health coaching intervention through multiple channels, including health plan population health outreach (36%), wellness offerings for employers (26%), direct provider referrals (22%), non-profit engagement (6%), and others (10%). Participants did not incur out-of-pocket costs associated with PackHealth engagement. Weblink invitations to complete the survey were delivered via text message or emailed from the PackHealth coaching platform based on patient communication preference. The weblink opened a unique webpage through which participants completed the survey. Response rates averaged 87% across all digital health coaching programs. Deidentified data was used for secondary analysis.

Measures

Demographic measures included age (years), sex, race (white; black; other/multi), and median household income of one's zip code. Insurance status was measured and classified as private insurance, Medicare, Medicaid, other Insurance, or uninsured. Employment status was classified as employed, self-employed, retired, "homemaker," unable to work, or student. Perceived stress was measured using a validated 4-item measure of stress, ranging from 0 to 16, with higher scores indicating higher stress.¹⁰ Health-related quality of life (HRQOL) was assessed using PROMIS-GHQ-10, a measure of overall physical and mental health appropriate for both the general population and those living with chronic conditions. We used 8 of the items from the GHQ-10 to calculate separate summary measures of mental (4 items) and physical well-being (4 items).¹¹

Financial toxicity

The COmprehensive Score for financial Toxicity (COST) patient-reported outcome measure (PROM) is an 11-item scale previously validated among patients with AJCC stage IV solid tumors receiving chemotherapy.⁸ The present research assessed the psychometric properties of COST and its correlations with HRQOL in a sample of patients with chronic diseases. Our analytic procedures closely mirrored those of de Souza et al⁸ to facilitate comparison of the psychometric properties of the scale when measuring financial toxicity in individuals with chronic conditions rather than individuals with stage IV solid tumors and actively receiving chemotherapy. The COST scale scores were calculated based on FACIT documentation instructions (Comprehensive Score for financial Toxicity [COST] scoring Guidelines, Version 2, available online at www.facit.org). Consistent with scoring of other FACIT measures, higher scores indicated "better" outcomes and lower financial toxicity. Missing data on individual COST items were

mean-imputed for individuals with valid responses on at least 6 items, consistent with recommendations for handling item-missingness on Functional Assessment of Cancer Therapy (FACT-G) measures of quality of life.¹²

Reliability and validity of COST

The *internal consistency reliability* of COST was assessed using Cronbach's alpha, with values between .80 and .90 considered an indicator of very good reliability.¹³ We assessed the factor structure of COST using exploratory factor analysis and assessed model fit of 1- and 2-factor using confirmatory factor analysis. Additional information about these analyses is available in Supporting Information. *Convergent validity* was assessed via the partial Pearson correlation coefficient between COST and perceived stress. The *divergent validity* analysis could not be replicated because the Marlowe-Crowne Social Desirability Scale¹⁴ was not collected.

Factors associated with financial toxicity among individuals with chronic conditions

Consistent with the validation steps of de Souza et al⁸ "known groups" validity was assessed by testing for expected differences in the conditional mean of COST scores, including perceived stress, insurance status, and employment status. We tested if individuals who reported being unemployed differed from employed individuals on the COST measures (better financial outcomes). We also tested if individuals with private insurance had higher COST measures compared to those relying on Medicaid (ie, insurance for the individuals near the poverty line) or those who were uninsured, independent of sex, race, and age. In both instances, the comparison metrics carry significant information about the individual's financial status.

Statistical analysis

We tested for differences in mean COST scores by participant demographics, employment status, stress, and PROMIS measures of mental and physical well-being. Group differences in mean COST scores were assessed using least squares regression. Variables with statistically significant differences in mean COST scores were included as covariates in subsequent multivariable analyses. For comparison with de Souza et al,⁸ we reported Pearson partial correlation coefficients between COST and PROMIS measures of mental and physical well-being, respectively, controlling for age, sex, race, employment status, median household income, insurance status, and perceived stress. The supplemental analyses performed by the original authors are also reproduced and presented in Appendix A.

Results

A total of 2798 individuals completed the survey. Table 1 presents mean COST values by respondent characteristics for

individuals with at least 6 valid responses to the 11-item COST scale (n = 2771). Significant mean differences in mean COST scores were observed across all participant characteristics examined, including age category ($P = .0007$), sex ($P < .0001$), race ($P < .0001$), income ($P < .0001$), and employment status ($P < .0001$). The majority of survey respondents were female (77%), white (64%), with the plurality of respondents between 51 and 64 years of age (47%). Most respondents reported being employed (67%) and having private insurance (77%).

Reliability and validity

The COST measure of financial toxicity demonstrated very good internal consistency (Cronbach's alpha = .89). Cronbach alpha scores greater than .90 may indicate that some items can be removed from the scale to reduce redundancy.¹³ Convergent validity was assessed via the Pearson correlation coefficient between COST and perceived stress; as expected, a significant negative correlation was observed ($r = -.48$, $P < .0001$), indicating that higher COST scores (better financial well-being) were associated with lower levels of stress.

Table 2 presents results from a multivariate ordinary least squares (OLS) regression predicting COST scores controlling for a range of respondent characteristics. On average, black respondents had lower COST scores relative to white respondents ($b = -0.82$, $P = .0284$), indicating greater financial toxicity in that population. Individuals who indicated belonging to more than 1 race category, or a category other than white or black, had lower COST scores relative to white respondents ($b = -3.03$, $P = .0003$). Regarding uninsured individuals and those relying on Medicaid, they had substantially lower COST scores relative to those with private insurance ($b = -7.49$, $P < .001$; $b = -4.92$, $P < .001$, respectively). However, employment status was not associated with differences in COST scores. Regarding the association between COST and HRQOL measures, higher PROMIS and Mental PROMIS Physical well-being scores were associated with higher COST scores ($b = 0.13$, $P < .0001$; $b = 0.28$, $P < .0001$, respectively), indicating that less financial toxicity was associated with better HRQOL.

Further, and consistent with the analyses of de Souza et al,⁸ we found a significant correlation between COST and measures of HRQOL. Specifically, the Pearson correlation coefficient between COST and PROMIS Physical well-being was significant ($r = .46$; $P < .0001$); after adjusting for age, sex, race, employment status, insurance status, area median income, PROMIS Mental well-being, and stress, the Pearson partial correlation coefficient remained significant ($r = .21$, $P < .0001$). The Pearson correlation coefficient between COST and PROMIS Mental well-being was also significant ($r = .45$; $P < .0001$); after adjusting for the same set of covariates, the Pearson partial correlation coefficient remained significant ($r = .10$, $P < .0001$). Overall, results from a sample of participants with chronic disease and enrolled in a health coaching

Table 1. Patient characteristics and COST values (N=2755).

VARIABLE	N	COST MEAN	SD	P
Age categories				
LT 50	1090	26.7	10.1	.0007
51-64	1292	27.6	9.9	
65-75	290	29.1	9.4	
GT 75	83	28.8	9.4	
Sex				
Female	2124	27.0	9.9	<.0001
Male	625	29.0	9.7	
Race				
White	1742	27.9	9.8	.0004
Black	839	27.1	9.7	
Other/Multi	114	24.9	11.3	
Refuse	31	23.1	11.7	
Median household income				
Q1	725	26.5	10.0	<.0001
Q2	684	27.1	9.6	
Q3	683	27.2	9.9	
Q4	679	29.1	10.0	
Insurance status				
Private	2189	28.4	9.4	<.0001
Medicare	296	26.0	9.9	
Medicaid	75	18.8	10.5	
Other	21	26.2	9.9	
Uninsured	63	16.2	10.2	
Employment status				
Employed	1809	28.5	9.1	<.0001
Self employed	95	26.7	10.5	
Unemployed	76	21.0	10.7	
Retired	395	29.3	9.4	
Homemaker	81	24.8	9.6	
Unable	193	18.7	10.2	
Student	24	23.5	12.0	
Refused	34	25.0	12.7	
Stress quartile				
Q1	743	32.2	8.4	<.0001
Q2	486	30.4	8.2	

(Continued)

Table 1. (Continued)

VARIABLE	N	COST MEAN	SD	P
Q3	851	26.8	8.9	
Q4	691	21.1	10.0	
PROMIS mental quartile				
Q1	654	21.3	10.2	<.0001
Q2	784	26.3	9.0	
Q3	520	29.4	8.4	
Q4	813	32.3	8.2	
PROMIS physical quartile				
Q1	717	21.4	10.1	<.0001
Q2	532	26	9.1	
Q3	690	28.9	8.6	
Q4	832	32.4	8.1	

program indicate that financial toxicity is associated with mental and physical HRQOL after adjusting for sociodemographic characteristics.

Conclusions and Discussion

The current study's results are consistent with those found by de Souza et al⁸—generally. The study demonstrates that the COST instrument has the potential to be used in populations beyond those with cancer to assess financial toxicity. In particular, we were able to replicate convergent validity of the COST instrument with the HRQOL scale. The statistically significant correlation with the HRQOL scale indicates that the COST instrument is a clinically relevant, PRO that can be used with a variety of diseases.

The current study has 3 distinct strengths over the earlier study. First, the sample was considerably larger and more diverse. As work moves forward to demonstrate the generalizability of the COST instrument, such large-scale studies in diverse populations will be needed. Having such studies will allow for better calibration of the summated score thresholds that indicate an individual is experiencing financial toxicity. A second advantage of this study is that the financial toxicity effect sizes these participants were likely to have experienced were smaller than those with end-stage cancer. Demonstrating that the instrument has a high degree of positive predictive power increases its utility across a number of patient populations. The correlations between individuals studied in this population and those in the prior cancer study were very similar. Lastly, the COST survey was administered as part of a general wellness interview rather than cancer specific discussion of the patient's financial burdens. When administered, the framing of the survey is important because respondents may make different inferences for how to interpret items. In the earlier cancer

Table 2. Results from an OLS regression predicting financial toxicity scores (N=2402).

VARIABLE	B	SE	(95% CI)	P
Intercept	12.40	2.07	(2.07378)	<.0001
Age	0.00	0.02	(0.01663)	.8408
Sex				
Male	REF			
Female	-0.76	0.40	(0.39766)	.0558
Race				
White	REF			
Black	-0.82	0.38	(0.376)	.0284
Other/multi	-3.03	0.84	(0.8367)	.0003
Refuse	-3.57	1.56	(1.56325)	.0223
Median household income (10 000)	0.01	0.00	(0)	.2282
Insurance status				
Private	REF			
Medicare	-0.40	0.66	(0.65728)	.5464
Medicaid	-4.92	1.07	(1.0748)	<.0001
Other	0.88	1.94	(1.94249)	.6519
Uninsured	-7.49	1.21	(1.21123)	<.0001
Employment status				
Unemployed	REF			
Employed	1.83	1.11	(1.11375)	.1004
Self employed	0.06	1.39	(1.39034)	.9664
Retired	2.76	1.19	(1.18611)	.0200
Homemaker	0.63	1.42	(1.41963)	.6593
Unable	-1.33	1.23	(1.22935)	.2774
Student	-1.73	2.09	(2.09378)	.4079
Refused	1.37	1.93	(1.93308)	.4772
Stress score	-0.87	0.07	(0.06518)	<.0001
PROMIS mental score	0.13	0.03	(0.02755)	<.0001
PROMIS physical score	0.28	0.03	(0.02694)	<.0001

study, the conversation was specifically about the impact of the treatment regime on the patient's financial status. Hence, every item was likely considered to be related to that construct. Alternatively, if the survey is administered without being part of a specific disease discussion, some of the items may fall into a construct that is not disease specific. The confirmatory factor analyses contained in the supplemental sections of both this paper and the prior work have different findings.

The supplemental analysis in the study-at-hand found that the 11 items of the COST instrument loaded on 2 factors, contrast to a previous study finding the measure to be unidimensional.⁸ Further research is needed to assess how the 2-dimension solution relates to convergent and divergent validity. It is possible that a shorter scale may be developed, further increasing the tool's utility by decreasing the respondent burden.

Limitations and Future Research

The research team used data from PackHealth, a third-party vendor for wellness counseling. In our efforts to replicate research reported in de Souza et al,⁸ we lacked 2 pieces of information which were not collect: detailed income data and psychometric scales used to assess discriminant reliability as articulated in the health-related quality of life (HRQOL) measure. However, these missing data did not affect our ability to reproduce comparable results to the original authors in terms of convergent validity and correlations with HRQOL. Rather, analyses expanded the application of the COST instrument and suggest areas of scale refinement to expand its utility beyond cancer patients and include a variety of health issues.

In addition to further examining the 2-dimension solution factor loadings and refining measures of financial toxicity for individuals managing chronic conditions, our next step is to determine whether changes in financial toxicity are associated with changes in physical and mental well-being. Though the data available are self-reported, if improvements in financial toxicity are associated with improved physical and mental well-being, it suggests that the management of chronic conditions might be enhanced by helping patients navigate care costs more efficiently.

Author Contributions

Dr. Pavela conducted the data analysis and drafted the research methods and results sections. Dr. Fifolt drafted the discussion section. Ms. Tison drafted the conclusions section. Mr. Allison prepared the data and co-wrote the results sections. Mr. Burton collected and collated the datasets and drafted the sampling design passages. Dr. Ford wrote the introduction, abstract, and future research sections.

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Appendix A

Supplemental analysis

These materials describe the results of analyses examining the factor structure of the COST measure of financial toxicity in a sample of individuals with chronic conditions. The COST measure was previously described and validated in a sample of patients with Stage IV cancer.⁸ One goal of this paper was to compare the performance of COST among individuals characterized by a different and perhaps less severe health issue: having a chronic condition, including cardiometabolic, autoimmune, respiratory, cancer, mental health, and specialized or rare conditions. Whereas de Souza et al⁸ found COST to be unidimensional in patients with cancer, our results suggest a 2-dimensional latent structure in a population of individuals managing chronic disease (see Table A1).

After estimating the reliability of COST, we assessed its dimensionality with an exploratory factor analysis using Varimax rotation to produce orthogonal factors. Results indicated a 2-factor solution accounted for much of the variation in observed responses to COST items. Figure A1 presents a Scree Plot, plotting factors against associated eigenvalues, and is supportive of a 2-factor model.

Next, we conducted confirmatory factor analyses (CFA) for 1- and 2-factor models, respectively. While the exploratory factor analysis indicated a 2-factor model was preferable to a 1-factor model, we conducted CFA for both models to compare our results with those of the 1-factor CFA analysis reported in de Souza et al.⁸ Specifically, it was reported in the Supplemental Materials of de Souza et al⁸ that "SEM revealed excellent fit for the single factor model. Fit indices included: chi-squared/df=2.44, comparative fit index (CFI)=0.94, Tucker-Lewis Index (TLI)=0.93, root mean squared error of approximation (RMSEA)=0.08, and standardized root mean squared residual (SRMR)=0.04.⁵ Every COST item met criteria for practical significance with loadings of 0.60 or above. . ." (p. 3).

In contrast, results from our 1-factor CFA indicated a poor fit to the data, with a chi-squared/df=57.9, comparative fit (CFI)=.81, root mean squared error of approximation (RMSEA)=.14, and standardized root mean squared residual (SRMR)=.0841). These results suggest that the COST measure of financial toxicity has a different dimensional structure among individuals with chronic conditions. Therefore, refinement of the measure may be warranted to improve its validity in this population.

Table A1. Two factor solution for COST instrument.

ITEM	FACTOR 1 LOADING	FACTOR 2 LOADING
Question 1: I know that I have enough money in savings, retirement, or assets to cover the costs of my treatment	16	72
Question 2: My out-of-pocket expenses are more than I thought they'd be	72	16
Question 3: I worry about the financial problems I will have in the future as a result of my illness or treatment.	79	28
Question 4: I feel I have no choice about the amount of money I spend on care	76	6
Question 5: I am frustrated that I cannot work or contribute as much as I usually do	69	25
Question 6: I am satisfied with my current financial situation	17	83
Question 7: I am able to meet my monthly expenses	18	79
Question 8: I feel financially stressed	47	61
Question 9: I am concerned about keeping my job and income, including work at home	58	29
Question 10: My cancer or treatment has reduced my satisfaction with my present financial situation	76	27
Question 11: I feel in control of my financial situation	31	77

Printed values are multiplied by 100 and rounded to the nearest integer.

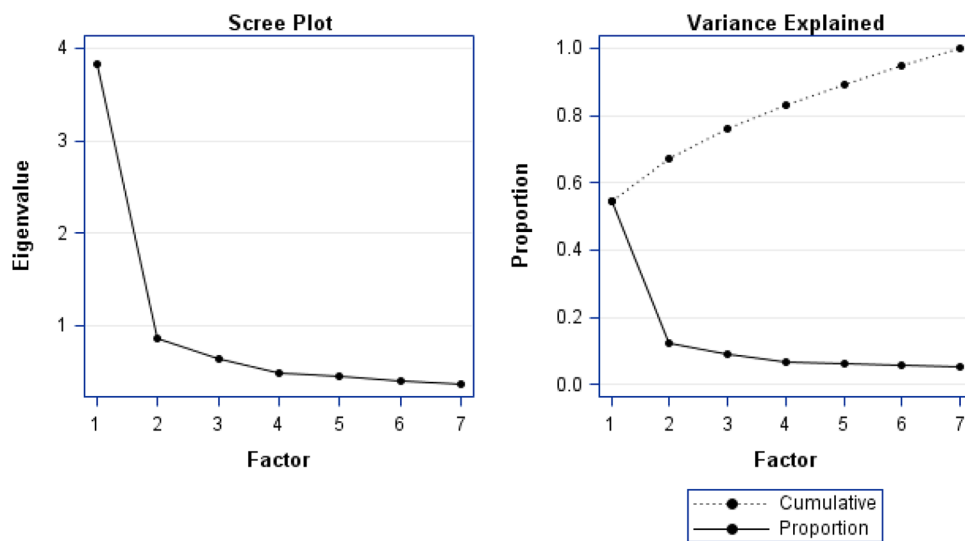


Figure A1. Scree plot of COST factors.