Measurement and Validation of the Comprehensive Score for Financial Toxicity (COST) in a Population With Diabetes

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OBJECTIVE

The Comprehensive Score for Financial Toxicity–Functional Assessment of Chronic Illness Therapy (COST-FACIT) is a validated instrument measuring financial distress among people with cancer. The reliability and construct validity of the 11-item COST-FACIT were examined in adults with diabetes and high A1C.

RESEARCH DESIGN AND METHODS

We examined the factor structure (exploratory factor analysis), internal consistency reliability (Cronbach α), floor/ceiling effects, known-groups validity, and predictive validity among a sample of 600 adults with diabetes and high A1C.

RESULTS

COST-FACIT demonstrated a two-factor structure with high internal consistency: general financial situation (7-items, α = 0.86) and impact of illness on financial situation (4-items, α = 0.73). The measure demonstrated a ceiling effect for 2% of participants and floor effects for 7%. Worse financial toxicity scores were observed among adults who were women, were below the poverty line, had government-sponsored health insurance, were middle-aged, were not in the workforce, and had less educational attainment ($P < 0.01$). Worse financial toxicity was observed for those engaging in cost coping behaviors, such as taking less or skipping medicines, delaying care, borrowing money, "maxing out" the limit on credit cards, and not paying bills ($P < 0.01$). In regression models for the full measure and its two factors, worse financial toxicity was correlated with higher A1C ($P < 0.01$), higher levels of diabetes distress ($P < 0.01$), more chronic conditions ($P < 0.01$), and more depressive symptoms ($P < 0.01$).

CONCLUSIONS

Findings support both the reliability and validity of the COST-FACIT tool among adults with diabetes and high A1C levels. More research is needed to support the use of the COST-FACIT tool as a clinically relevant patient-centered instrument for diabetes care.

More than 30 million Americans have a diagnosis of diabetes (1). Glycemic control is an important outcome of diabetes management and requires adopting numerous behaviors, including regular exercise and weight management, taking medications, and regularly monitoring blood glucose levels (2). For many people, the multiple

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services and supplies required to manage diabetes and its comorbidities result in significant financial burdens, emotional distress, and unmet basic needs. One-half of United States adults with diabetes report financial stress, and nearly one-quarter experience high out-of-pocket health care burden and food insecurity (3). On average, people with diabetes have medical expenditures that are approximately twice as high as comparable individuals without diabetes (1). Individuals with diabetes report alarming rates of cost-related nonadherence (CRN) that range from 20 to 40% (4). CRN among people with diabetes is associated with high A1C levels, more symptoms, and declines in functioning (4). Over time, patients with cardiovascular disease, including diabetes, who use less of their medication than prescribed because of cost concerns are more likely to be hospitalized (5).

Our understanding of financial burden and stress associated with diabetes management is primarily derived from national studies that used single-item measures that capture or serve as proxies for financial stress, out-of-pocket expenditures, and behavioral responses to cost pressures. There are no validated multi-item scales in the diabetes literature that assess the financial stress associated with disease management in a more comprehensive and potentially accurate manner. In the cancer literature, the term financial toxicity was coined as referring to a common side effect of cancer treatment (6). Specifically, financial toxicity describes the material conditions that arise from greater expenses and lower income, the psychosocial response to those material conditions, and the coping behaviors that patients and their families adopt to manage their care, condition, and financial situation (6). In 2014, a patient-reported outcome measure called the Comprehensive Score for Financial Toxicity–Functional Assessment of Chronic Illness Therapy (COST-FACIT) (version 1) was developed and validated among patients with breast, lung, or colorectal cancer (7). The COST-FACIT measure consists of 11 statements that measure financial toxicity, with respondents rating each statement on a five-point Likert scale. Lower scores represent worse financial toxicity. Among patients with cancer, the COST-FACIT measure has shown a one-factor structure (i.e., covariance among items measures a single factor, financial toxicity), excellent reliability and validity in measuring financial toxicity, and strong correlation with health-related quality of life (8). Recently, Esselen et al. (9) examined the frequency of financial toxicity at different COST-FACIT score levels and the association with cost coping strategies, such as medication noncompliance, borrowing money, and changing spending habits, among patients with gynecological cancers. On the basis effect sizes of quality-of-life scores developed by the original proposers of the measure, they found that increasing severity levels of financial toxicity were associated with worsening medication adherence.

We sought to adapt and assess the suitability of the COST-FACIT measure (version 1) for use in people with diabetes. In this study, we examined the reliability and construct validity of the 11-item measure in a population with diabetes and high A1C levels. First, we attempted to replicate the one-factor structure of the COST-FACIT and then examined the internal consistency reliability, floor and ceiling effects, and convergent and known-groups validity of the measure. We hypothesized that COST-FACIT scores would be worse among individuals with more demographic risk factors and cost coping behaviors that suggest socioeconomic vulnerabilities.

RESEARCH DESIGN AND METHODS

Data Source

This study is a secondary analysis of data collected as part of a larger intervention study. Data came from the baseline assessment of a randomized controlled trial that is testing approaches to addressing unmet social risk factors in people with diabetes and high A1C levels (10). Data for the current study came from interviewer-assisted patient surveys. All study procedures were approved by the University of Michigan Institutional Review Board.

Sample

Potential participants were initially identified through the University of Michigan's Diabetes Research Registry (11) and the electronic health record through Michigan Medicine. Study participants met the following criteria: *1*) 18–75 years of age, *2*) diagnosis of type 1 or type 2 diabetes with prescribed oral or injectable antihyperglycemic medication, *3*) most recent (within the past 6 months) recorded A1C level of $\geq$7.5% for individuals aged $\leq$70 years and $>$8.0% for individuals between 70 and 75 years in age, *4*) positive report of financial burden or CRN using screening questions developed and validated from previous work (12,13), and *5*) access to a mobile phone. Exclusion criteria included significant cognitive impairment that precluded individuals from completing the study as evidenced by an inability to complete study intake procedures. Individuals actively participating in another diabetes-related research study were also excluded.

Trained recruitment staff made initial contact with potential participants by telephone and screened them for inclusion/exclusion. Participants who met inclusion criteria completed informed consent for trial participation by telephone before their baseline assessments. All participants received a monetary incentive for their participation.

A total of 6,055 potential participants were initially contacted, of whom 997 were confirmed to be eligible. Of those, 666 (66%) consented to participate, and 600 provided completed surveys. This analysis is based on 600 surveys with complete data on the COST-FACIT measure.

Measures

In-person interviewer-assisted surveys were conducted by trained staff before March 2020, when the World Health Organization declared the coronavirus disease 2019 pandemic. Since then, surveys were administered over the telephone.

COST-FACIT

Financial toxicity was assessed with the 11-item COST-FACIT measure (7). As in the original measure, each item was measured on a five-point Likert scale (0 = not at all, 4 = very much), with recall based on the past 7 days related to the participant's diabetes management. The only changes made to the original version of the measure were to refer to diabetes management instead of cancer treatment. A score was computed by first reverse coding six items, then taking the sum of all items, multiplying the sum by 11, and dividing that number by the number of items answered. Lower scores indicate higher financial toxicity.

Demographic and Clinical Characteristics

Standard demographic characteristics were collected, including age, sex, self-reported annual income, educational attainment, employment status, health insurance status, self-reported race/ethnicity, marital status, and monthly out-of-pocket expenses for managing diabetes. Using income and household information, participants were classified using percentiles relative to the United States poverty level for 2019 (14). Other data collected included length of time since diagnosis of diabetes, number of chronic conditions, and type of diabetes (type 1 or type 2). Additional clinical measures included the two-item validated Diabetes Distress Scale (15). Higher scores indicated greater distress. A1C was measured at the time of the baseline survey using the DCA Vantage Analyzer for interviews conducted in person (16). For participants surveyed by telephone, A1C values were collected by the A1C Now home test kit (17). A1C was statistically calibrated to account for data collection method. Blood pressure was measured as systolic blood pressure/diastolic blood pressure in millimeters of mercury (e.g., 120/80 mmHg) with an automated blood pressure machine (18). Depressive symptoms were measured using the four-item Patient Health Questionnaire, with higher scores indicating greater severity of symptoms (19). Diabetes self-management was measured using the 10-item Diabetes Self-Care Activities Scale, which assesses the frequency of specific behaviors in the past 7 days (e.g., following a healthy diet, physical activity, blood glucose testing, medication adherence) (20). Participants responded using a scale of 1–7 days, and mean scores are reported for each subdomain. Higher scores indicate better self-care.

Cost Coping Behaviors

We assessed cost coping behaviors with 10 individual items from validated measures and national surveys (21,22). Specifically, participants were asked whether they engaged in any of the following behaviors during the past 12 months because of financial burden of diabetes: took less medications, skipped medication doses, delayed or decided not to fill a prescription, and delayed or decided not to see a health care provider (four-point Likert scale from never to often) (21). We also asked participants how often over the past 6 months they borrowed money from someone, overdrafted their checking account, "maxed out" the limit on one or more credit cards, or did not pay bills on time (five-point Likert scale from never to always) (22). These behaviors were analyzed as dichotomous variables, with often and always indicating yes. The percentage of participants with a positive response is reported for each of the 10 items.

Statistical Analysis

Descriptive statistics were used to characterize the sample and the frequency of each COST-FACIT item. Exploratory factor analysis was used to explore the factor structure of the COST-FACIT scale using principal components extraction with varimax rotation (23). Items with factor loadings >0.60 were considered factor specific and of statistical and practical significance (24). Cronbach α was used to evaluate internal consistency of each factor, and a critical cutoff of 0.70 was considered minimal acceptable reliability (25). Floor and ceiling effects were calculated by identifying the proportion of participants who had either the lowest or the highest possible scores for the COST-FACIT and whether $>25\%$ of participants had minimum and maximum scores (26). A range of 5 was used to denote minimum and maximum scores, consistent with other work (27). Individuals with total scores between 0 and 5 were considered to have floor effects, and those with scores between 39 and 44 were considered to be at the ceiling. Known-groups differences for demographic characteristics and cost coping behaviors were computed using ANOVA. Linear regression models were used to assess correlations between COST-FACIT scores and A1C, systolic blood pressure, diabetes distress, diabetes self-care, number of chronic health conditions, and depressive symptoms. All statistical analyses were computed using R statistical software. $P < 0.05$ was considered significant.

RESULTS

Sample Characteristics

A total of 600 participants were included in the analytic sample (Table 1). On average, participants were 53 years of age (SD 13), 55% (n = 334) were female, 35% (n = 210) reported non-White race, and 87% (n = 520) reported some college education or above. Twelve percent (n = 73) were classified as living on incomes $<100\%$ of the poverty level, 16% (n = 95) 100–200% of the poverty level, 44% (n = 260) 201–400% of the poverty level, and 28% (n = 164) $\geq 401\%$ of the poverty level. The mean number of baseline unmet social needs was five (SD 5). Fifty-three percent of participants (n = 318) reported not being in the workforce, and 98% (n = 589) reported having either public or private health insurance. Mean years living with diabetes was 15 (SD 11), mean A1C was 8.2% (SD 1.5%), and mean systolic blood pressure was 133 mmHg (SD 19 mmHg). Participants were managing a mean number of four (SD 2.3) chronic conditions, and 46% (n = 273) reported taking seven or more medications. Twenty-eight percent (n = 165) reported moderate to severe depressive symptoms, and 63% (n = 377) reported high diabetes-related distress. Eighty-five percent (n = 509) of participants reported high social support.

COST-FACIT Scale

The median COST-FACIT score was 18.7 (mode 22, interquartile range 14). The measure demonstrated relatively insignificant floor effects (7%, n = 42) and ceiling effects (2%, n = 14).

For individual scale items (Table 2), the highest percentage of participants endorsed quite a bit/very much for "worry of financial problems in the future as a result of illness or treatment" (60%), and feeling that they "have no choice about money spent on care" (64%). Although nearly one-half endorsed quite a bit/very much for "I am able to meet my monthly expenses" (45%), just as many participants (42%) noted quite a bit/very much for "my out-of-pocket medical expenses are more than I thought they would be," "I am financially stressed" (47%), and "I am frustrated that I cannot work or contribute as much as I usually do" (47%). Only 16% endorsed quite a bit/very much for "I am satisfied with my current financial situation."

Exploratory factor analysis revealed a two-factor structure from the 11 items: general financial situation (seven items, α = 0.86), and impact of illness on financial situation (four items, α = 0.73), which indicates excellent internal consistency (Table 2). A sensitivity analysis

Table 1—Sample characteristics

Factor	Full sample (N = 600), n (%)
Age (years), mean (SD)	53 (13)
<44	130 (22)
45–64	340 (57)
>65	130 (21)
Sex	
Female	334 (55)
Male	264 (44)
Other	2 (1)
Race	
Non-Hispanic White	388 (65)
Non-Hispanic Black	101 (17)
Hispanic	31 (5)
Asian	23 (4)
Multiple races	42 (7)
Other	13 (2)
Married or partnered	340 (57)
Income as percentage of poverty level	
<100	73 (12)
100–200	95 (16)
201–400	260 (44)
>400	164 (28)
Education	
Less than high school	9 (1)
High school graduate or GED	71 (12)
Some college	270 (45)
College degree	250 (42)
Employment	
Full time	203 (34)
Part time	47 (8)
Unemployed	31 (5)
Not in workforce	318 (53)
Has health insurance	589 (98)
Health insurance type	
None	11 (2)
Private	260 (43)
Medicare	44 (7)
Medicaid	79 (13)
Medicare + Medicaid supplemental	64 (11)
Medicare + private supplemental	140 (23)
Other	2 (1)
Average monthly out-of-pocket spending	
≤$100	161 (27)
$101–$500	372 (63)
≥$501	54 (9)
Unmet social needs, mean (SD)	5 (5)
Type of diabetes	
Type 1	130 (22)
Type 2	470 (78)
Years living with diabetes, mean (SD)	15 (11)
A1C (%), mean (SD)	8.2 (1.5)
Systolic blood pressure (mmHg), mean (SD)	133 (19)
Number of chronic conditions, mean (SD)	4 (2.3)
Number of medications	
1–2	51 (8)
3–4	113 (19)

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using the Oblimin rotation yielded similar results with a two-factor structure.

Known-Groups Comparisons of COST-FACIT Scores

Table 3 shows known-groups comparisons of COST-FACIT scores for the full measure and its two factors. Lower scores indicate worse financial toxicity.

For the full measure and its two factors, lower mean COST-FACIT scores were observed for women compared with men ($P < 0.01$) and those with incomes ≤200% of the poverty line compared with higher income ($P < 0.01$). No differences were observed between insured and uninsured participants; however, lower mean COST-FACIT scores were observed for those with Medicaid or Medicare only and Medicaid supplemental versus privately insured and Medicare with private supplemental insurance ($P < 0.01$).

For cost coping behaviors, lower mean COST-FACIT scores were observed for those who took less medication ($P < 0.001$), skipped medication doses ($P < 0.001$), delayed or decided not to fill a prescription ($P < 0.001$), delayed or decided not to see a health care provider because of cost ($P < 0.001$), borrowed money from someone ($P < 0.001$), or maxed out the limit on one or more credit cards ($P < 0.05$).

For the full measure and the general financial situation factor, lower mean COST-FACIT scores were observed for participants who were 45–64 years of age compared with ≤44 and ≥65 years of age, those who were single versus married ($P < 0.01$), those reporting unemployment or not in the workforce compared with being employed ($P < 0.01$), and those with less than a college degree compared with those with a college degree ($P < 0.01$). For cost coping behaviors, lower mean COST-FACIT scores were observed for those reporting overdrafting their checking account ($P < 0.01$) or not paying their bills on time ($P < 0.01$). For the full measure and impact of illness on financial situation factor, lower mean COST-FACIT scores were observed among those with higher average monthly out-of-pocket spending ($P < 0.01$). For the general financial situation factor, race differences were observed, with lower mean COST-FACIT scores among non-Hispanic Black

Table 1—Continued

Factor	Full sample (N = 600), n (%)
5–6	162 (27)
≥7	273 (46)
Depressive symptoms	
None	259 (43)
Mild	175 (29)
Moderate	94 (16)
Severe	71 (12)
Diabetes Distress Scale-2	
No distress	152 (25)
Moderate distress	71 (12)
High distress	377 (63)
Social support,* mean (SD)	25 (6)
Low	91 (15)
High	509 (85)

GED, General Educational Development. *Higher score = greater social support (score range 8–34).

participants compared with all other race/ethnicities.

Clinical and Self-Care Measures and Their Correlation With COST-FACIT Scores

Table 4 demonstrates the predictive validity of the clinical and self-care measures for diabetes and their correlation with COST-FACIT scores for the full measure and its two factors. In regression models for the full measure and its two factors, lower scores (worse financial toxicity) were correlated with higher A1C levels ($P < 0.01$), higher levels of diabetes distress ($P < 0.01$), and more depressive symptoms ($P < 0.01$). Higher scores (less financial toxicity) were associated with better medication management ($P < 0.01$). For the full measure and the general financial situation factor, lower scores were correlated with the presence of more chronic conditions ($P < 0.01$), and higher scores (less financial toxicity) were associated with more days of physical activity and greater attention to general diet.

CONCLUSIONS

To our knowledge, this study is the first in the literature to assess the reliability and validity of a measure for financial stress associated with diabetes management. We were able to demonstrate a two-factor structure with the COST-FACIT in our data: general financial situation and impact of illness on financial situation. The internal consistency of the COST-FACIT was comparable to both the original validation of the tool (7,8) and other studies that have validated the instrument in other languages demonstrating both one- and two-factor structures (28–30). Having lower COST-FACIT scores (worse financial toxicity) was associated with several important diabetes outcomes, including higher levels of diabetes distress and more depressive symptoms. Those with less financial toxicity engaged in more self-care for diabetes. While all participants in our study had A1C levels of at least 7.5%, worse COST-FACIT scores were associated with a higher A1C. Our findings provide strong psychometric evidence in support of financial toxicity as a relevant and clinically significant concept among people with diabetes and the COST-FACIT as a promising patient-reported outcome measure to assess patient perception of their general financial situation and

Table 2—COST-FACIT measure adapted for use in a diabetes population: exploratory factor analysis

	Rating of dimensions quite a bit/very much, %	Factor 1: general financial situation	Factor 2: impact of illness on financial situation
Internal consistency, α		0.86	0.73
Survey items*			
I know that I have enough money in savings, retirement, or assets to cover the costs of my treatment.	24	0.62	
I am frustrated that I cannot work or contribute as much as I usually do.	47	0.60	
I am satisfied with my current financial situation.	16	0.82	
I am able to meet my monthly expenses.	45	0.81	
I am financially stressed.	47	0.79	
I am concerned about keeping my job and income, including work at home.	21	0.58	
I feel in control of my financial situation.	22	0.82	
My out-of-pocket medical expenses are more than I thought they would be.	42		0.73
I worry about the financial problems I will have in the future as a result of my illness or treatment.	60		0.69
I feel I have no choice about the amount of money I spend on care.	64		0.77
My diabetes expenses have reduced my satisfaction with my present financial situation.	30		0.64

*Each statement was assessed on a 5-point Likert scale (not at all to very much). Responses were assessed as they apply to the participants' diabetes in the past 7 days. Adapted with permission from FACIT and The University of Chicago.

Table 3—Known-groups comparisons of COST-FACIT scores for the full measure and its two factors

Demographic characteristic	COST-FACIT 11-item total score*	*P*†	Factor 1: general financial situation‡	*P*	Factor 2: impact of illness on financial situation§	*P*
Age (years)		<0.01		<0.01		0.10
<44	19.1 (8.3)		12.2 (6.5)		6.7 (4.0)	
45–64	17.9 (9.5)		11.0 (7.1)		6.4 (3.7)	
>65	21.6 (10.2)		13.6 (7.4)		7.3 (4.1)	
Sex		<0.01		<0.01		<0.01
Female	17.2 (8.8)		10.5 (6.7)		6.2 (3.7)	
Male	21.1 (9.9)		13.4 (7.4)		7.2 (4.0)	
Race		0.06		<0.01		0.49
Non-Hispanic White	19.5 (9.8)		12.4 (7.3)		6.6 (4.0)	
Non-Hispanic Black	16.3 (9.1)		9.1 (6.5)		6.7 (4.0)	
Hispanic	19.7 (7.7)		12.5 (6.0)		6.5 (2.7)	
Asian	19.6 (7.1)		13.4 (5.6)		5.9 (3.4)	
Multiple races	19.8 (9.2)		11.6 (7.2)		7.6 (3.6)	
Other	16.9 (9.4)		10.8 (7.2)		5.5 (3.1)	
Married or partnered		<0.01		<0.001		0.20
Yes	20.2 (9.4)		12.9 (7.2)		6.8 (3.7)	
No	17.3 (9.4)		10.4 (6.8)		6.4 (4.2)	
Income as percentage of poverty level		<0.01		<0.001		0.02
<100	13.7 (6.6)		6.0 (4.5)		7.0 (4.0)	
100–200	14.6 (8.0)		7.8 (5.0)		6.3 (3.9)	
201–400	18.4 (9.2)		11.7 (6.5)		6.3 (3.9)	
>400	24.7 (9.0)		16.9 (6.5)		7.3 (3.8)	
Education		0.01		<0.001		0.42
Less than high school	18.9 (8.1)		10.1 (5.8)		8.0 (4.7)	
High school graduate or GED	16.2 (8.9)		9.0 (6.0)		6.8 (4.3)	
Some college	18.4 (9.4)		11.0 (7.0)		6.8 (3.9)	
College degree	20.3 (9.6)		13.6 (7.2)		6.4 (3.7)	
Employment		<0.01		<0.001		0.26
Full time	22.1 (8.8)		15.2 (6.1)		6.8 (3.8)	
Part time	20.2 (8.8)		12.6 (6.6)		7.5 (4.1)	
Unemployed	17.0 (9.5)		9.7 (7.1)		6.4 (3.7)	
Not in workforce	16.5 (9.5)		9.7 (7.0)		6.4 (3.9)	
Has health insurance		0.60		0.40		0.90
Yes	19.0 (9.5)		11.9 (7.1)		6.6 (3.9)	
No	17.5 (9.7)		10.1 (6.5)		6.8 (4.9)	
Health insurance type		<0.01		<0.001		0.01
Private	21.2 (8.9)		14.6 (6.5)		6.4 (3.6)	
Medicare	14.9 (8.5)		8.7 (6.0)		5.6 (3.4)	
Medicaid	15.4 (8.5)		7.3 (6.0)		7.7 (4.0)	
Medicare + Medicaid supplemental	15.2 (8.5)		7.2 (5.7)		7.3 (4.2)	
Medicare + private supplemental	19.8 (10.5)		12.5 (7.3)		6.5 (4.1)	
Average monthly out-of-pocket spending		<0.01		0.17		<0.001
≤$100	22.1 (10.1)		12.7 (7.7)		8.9 (4.1)	
$101–$500	18.0 (8.8)		11.5 (6.8)		6.0 (3.5)	
≥$501	16.6 (9.8)		12.0 (7.4)		4.2 (3.5)	
Cost coping behaviors						
Took smaller doses of diabetes medicine		<0.001		<0.001		<0.001
Yes	13.3 (7.8)		8.4 (5.9)		4.6 (3.2)	
No	20.0 (9.4)		12.5 (7.2)		7.1 (3.9)	
Skipped doses to make diabetes medicine last longer		<0.001		<0.001		<0.001
Yes	13.2 (8.0)		8.4 (6.0)		4.4 (3.2)	
No	19.9 (9.4)		12.4 (7.1)		7.0 (3.9)	
Delayed getting diabetes prescription filled		<0.001		<0.001		<0.001
Yes	14.3 (7.6)		9.4 (6.2)		4.6 (3.2)	
No	20.5 (9.6)		12.6 (7.2)		7.3 (3.8)	

Continued on p. 2541

Table 3—Continued

Demographic characteristic	COST-FACIT 11-item total score*	P†	Factor 1: general financial situation‡	P	Factor 2: impact of illness on financial situation§	P
Decided not to fill diabetes prescription		<0.001		<0.001		<0.001
Yes	14.8 (8.5)		9.6 (6.7)		4.8 (3.5)	
No	19.8 (9.5)		12.3 (7.1)		7.0 (3.9)	
Delayed seeing a health care provider for diabetes		<0.001		<0.001		<0.001
Yes	13.9 (7.3)		8.8 (5.8)		4.7 (3.5)	
No	20.1 (9.6)		12.5 (7.2)		7.1 (3.8)	
Did not see health care provider for diabetes		<0.001		<0.001		<0.001
Yes	13.2 (6.5)		8.2 (5.7)		4.6 (3.1)	
No	19.7 (9.6)		12.3 (7.2)		6.9 (3.9)	
Borrowed money from someone		<0.001		<0.001		0.01
Yes	10.4 (6.5)		4.9 (4.4)		5.1 (3.7)	
No	19.6 (9.4)		12.3 (7.0)		6.7 (3.9)	
Overdrafted checking account		<0.01		<0.001		0.55
Yes	12.3 (7.1)		5.7 (5.1)		6.2 (4.2)	
No	19.4 (9.5)		12.2 (7.1)		6.6 (3.8)	
Maxed out the limit on one or more credit cards		<0.001		<0.001		0.05
Yes	13.8 (7.6)		7.8 (5.3)		5.7 (3.6)	
No	20.4 (9.5)		13.2 (7.0)		6.7 (3.8)	
Did not pay bills on time		<0.01		<0.001		0.89
Yes	13.8 (8.1)		6.6 (5.7)		6.8 (3.9)	
No	19.3 (9.5)		12.2 (7.1)		6.7 (3.9)	

Data are mean (SD). GED, General Educational Development. *Possible scores 0–48. †All *P* values by ANOVA. ‡Possible scores 0–28. §Possible scores 0–16.

the impact of treatment on economic well-being.

Several items of the COST-FACIT were endorsed as quite a bit/very much by nearly one-half of participants in our sample. Although close to one-half of participants reported that they were able to meet monthly expenses, just as many also endorsed feeling financially stressed, feeling like their out-of-pocket expenses are more than they thought they would be, worrying about financial problems in the future as a result of illness and treatment, and feeling frustrated that they cannot work or contribute as much as usual. These findings align with national studies that have demonstrated high rates of disability and absenteeism as a result of diabetes (1,31) and high out-of-pocket expenditures of patients for treatment and management costs annually (1). For example, a typical person with diabetes who has health insurance and is taking insulin could anticipate spending close to $5,000 a year in out-of-pocket costs (32).

Our findings align with recent systematic reviews on financial toxicity in cancer

Table 4—Clinical and self-care measures and their correlation with COST-FACIT scores for the full measure and its two factors

		COST-FACIT total scores		Factor 1: general financial situation		Factor 2: impact of illness on financial situation	
	Mean (SD)	β (SE)	P	β (SE)	P	β (SE)	P
A1C (%)	8.2 (1.5)	−0.9 (0.2)	0.01	−0.7 (0.1)	<0.001	−0.2 (0.1)	<0.01
Systolic blood pressure (mmHg)	133 (19.1)	0.01 (0.02)	0.71	−0.001 (0.01)	0.89	0.01 (0.01)	0.07
Diabetes distress*	3.7 (1.3)	−2.5 (0.26)	<0.01	−1.5 (0.2)	<0.001	−0.92 (0.11)	<0.001
Diabetes self-care†							
General diet	4.4 (1.9)	0.4 (0.19)	0.02	0.3 (0.1)	0.03	0.07 (0.08)	0.32
Specific diet	3.5 (1.7)	0.01 (0.22)	0.03	0.06 (0.1)	0.71	−0.05 (0.09)	0.53
Physical activity	2.6 (2.0)	0.54 (0.18)	<0.01	0.4 (0.1)	<0.001	0.08 (0.07)	0.28
Blood glucose testing	5.1 (2.4)	0.04 (0.16)	0.78	0.04 (0.1)	0.74	−0.02 (0.06)	0.73
Medication management	6.4 (1.1)	1.9 (0.50)	<0.001	1.2 (0.3)	<0.001	0.5 (0.2)	0.01
Number of chronic health conditions	4.2 (2.3)	−1.1 (0.17)	<0.01	−1.1 (0.1)	<0.01	−0.08 (0.07)	0.25
Depressive symptoms‡	3.8 (3.2)	−1.3 (0.10)	<0.001	−1.05 (0.07)	<0.001	−0.28 (0.04)	<0.001

*Possible scores 1.0–6.0, with higher scores indicating greater diabetes distress. †Possible scores 0.0–7.0, with higher mean indicating more days of adherence. ‡Possible scores 0.0–12.0, with higher scores indicating more symptoms of psychological distress; mean of ≥3 is considered positive for signs of depression.

(33–35), which concluded that a sizable proportion of patients experience these adverse effects. The current study also provides evidence that groups with known socioeconomic vulnerabilities (e.g., unemployed people, women, and those with higher out-of-pocket costs) experience high levels of financial toxicity. Other studies have documented that other factors required for effective management of diabetes and not typically covered by health insurance, such as a healthy diet, can be economically difficult to assess (36).

We found worse financial toxicity among participants engaging in cost coping strategies, such as cutting back on treatment and care, and adverse financial management behaviors, such as taking less or skipping medicines, delaying care, borrowing money, and not paying bills. While previous studies have shown that CRN is prevalent among people with diabetes (3,4), our study expands this work with implications that screening for financial toxicity may better identify a larger group of individuals at risk for CRN and provide opportunities for proactive outreach. This is being done more routinely in cancer settings (32), and our data suggest that interventions addressing financial toxicity would be as important in diabetes care.

There are limitations to this study that should be noted. The sample consisted of adults with diabetes, high A1C, and self-reported indication of unmet social determinants of health who had been recruited to an intervention study in one health system, therefore limiting the generalizability of the findings. We did not query participants about financial toxicity related to comorbidities, although this would be an important area of further exploration. Our sample had a high level of comorbid conditions that may contribute to financial toxicity experienced by the participants; thus, financial toxicity may be an underestimate. Despite range limitations in our A1C measures and our sample of adults who had all reported unmet social determinants of health, we were still able to detect significant correlations with financial toxicity. Although our sample was heterogeneous in terms of race/ethnicity, further work is warranted to assess the COST-FACIT measure across people with diabetes and varying levels of glycemic control and reported unmet social needs. Furthermore, with a random, heterogeneous sample of people with diabetes, a next step to this research would be to establish a clinically meaningful grading system similar to what has been established among people with cancer (8,9) and differentiating among levels of financial toxicity. Also important would be to further test briefer versions of the COST-FACIT scale for screening and intervention in clinical practice.

In conclusion, financial toxicity is a highly relevant construct among people with diabetes and high A1C levels and is correlated with engagement in cost coping behaviors. The COST-FACIT demonstrated strong psychometric properties and evidence of supporting validity in assessing financial toxicity among people with diabetes. COST-FACIT scores were associated with worse cardiovascular risk factor profiles and worse emotional well-being. More research is needed to support the use of the COST-FACIT as a clinically relevant patient-centered tool for diabetes care. Such validated tools are critically important to more effectively screen for and address financial toxicity among individuals with diabetes.

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References

1. American Diabetes Association. Economic costs of diabetes in the U.S. in 2017. Diabetes Care 2018;41:917–928
2. American Diabetes Association. 5. Lifestyle management: *Standards of Medical Care in Diabetes-2019*. Diabetes Care 2019;42(Suppl. 1): S46–S60
3. Patel MR, Piette JD, Resnicow K, Kowalski-Dobson T, Heisler M. Social determinants of health, cost-related nonadherence, and cost-reducing behaviors among adults with diabetes: findings from the National Health Interview Survey. Med Care 2016;54:796–803
4. Caraballo C, Valero-Elizondo J, Khera R, et al. Burden and consequences of financial hardship from medical bills among nonelderly adults with diabetes mellitus in the United States. Circ Cardiovasc Qual Outcomes 2020;13:e006139
5. Heisler M, Choi H, Rosen AB, et al. Hospitalizations and deaths among adults with cardiovascular disease who underuse medications because of cost: a longitudinal analysis. Med Care 2010;48:87–94
6. Zafar SY, Abernethy AP. Financial toxicity, part I: a new name for a growing problem. Oncology (Williston Park) 2013;27:80–81, 149
7. de Souza JA, Yap BJ, Hlubocky FJ, et al. The development of a financial toxicity patient-reported outcome in cancer: the COST measure. Cancer 2014;120:3245–3253
8. 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 2017;123:476–484
9. Esselen KM, Gompers A, Hacker MR, et al. Evaluating meaningful levels of financial toxicity in gynecologic cancers. Int J Gynecol Cancer 2021;31:801–806
10. Patel MR, Heisler M, Piette JD, et al. Study protocol: CareAvenue program to improve unmet social risk factors and diabetes outcomes–a randomized controlled trial. Contemp Clin Trials 2020;89:105933
11. Tan MH, Bernstein SJ, Gendler S, Hanauer D, Herman WH. Design, development and deployment of a Diabetes Research Registry to facilitate recruitment in clinical research. Contemp Clin Trials 2016;47:202–208
12. Pierre-Jacques M, Safran DG, Zhang F, et al. Reliability of new measures of cost-related medication nonadherence. Med Care 2008;46: 444–448
13. Burcu M, Alexander GC, Ng X, Harrington D. Construct validity and factor structure of survey-based assessment of cost-related medication burden. Med Care 2015;53:199–206
14. U.S. Census Bureau. 2019 Poverty thresholds. Accessed 1 March 2022. Available from https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-thresholds.html
15. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. Diabetes Care 2005;28:626–631
16. Szymezak J, Leroy N, Lavalard E, Gillery P. Evaluation of the DCA Vantage analyzer for HbA 1c assay. Clin Chem Lab Med 2008;46:1195–1198
17. Hirst JA, McLellan JH, Price CP, et al. Performance of point-of-care HbA1c test devices: implications for use in clinical practice - a systematic

review and meta-analysis. Clin Chem Lab Med 2017;55:167–180
18. Takahashi H, Saito K, Yakura N. Validation of Omron HEM-9200T, a home blood pressure monitoring device for the upper arm, according to the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization 81060-2:2013 protocol. J Hum Hypertens 2022;36:416–419
19. Kroenke K, Spitzer RL, Williams JB, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. Psychosomatics 2009;50:613–621
20. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. Diabetes Care 2000;23:943–950
21. National Center for Health Statistics. 2012 National Health Interview Survey. Accessed 1 March 2022. Available from https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm
22. Dew J, Xiao JJ. The financial management behavior scale: development and validation. Financ Couns Plan 2011;22:43
23. Rösler F, Manzey D. Principal components and varimax-rotated components in event-related potential research: some remarks on their interpretation. Biol Psychol 1981;13:3–26
24. Watkins MW. Exploratory factor analysis: a guide to best practice. J Black Psychol 2018;44:219–246
25. Tavakol M, Dennick R. Making sense of Cronbach's alpha. Int J Med Educ 2011;2:53–55
26. Birring SS, Bushnell DM, Baldwin M, et al. The psychometric properties of the King's Brief Interstitial Lung Disease questionnaire and thresholds for meaningful treatment response in patients with progressive fibrosing interstitial lung diseases. Eur Respir J 2022;59:2101790
27. Carlozzi NE, Kratz AL, Downing NR, et al. Validity of the 12-item World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) in individuals with Huntington disease (HD). Qual Life Res 2015;24:1963–1971
28. Chan DNS, Choi KC, Ng MSN, et al. Translation and validation of the Traditional Chinese version of the Comprehensive Score for Financial Toxicity-Functional Assessment of Chronic Illness Therapy (version 2). Health Qual Life Outcomes 2021;19:17
29. Yu HH, Bi X, Liu YY. Reliability and validity of the Chinese version on Comprehensive Scores for Financial Toxicity based on the patient-reported outcome measures. Zhonghua Liu Xing Bing Xue Za Zhi 2017;38:1118–1120 [in Chinese]
30. Pavela G, Fifolt M, Tison SE, Allison M, Burton BS, Ford EW. Re-validation of the Comprehensive Score for Financial Toxicity (COST): assessing the scale's utility in chronic disease populations. Health Serv Insights 2021;14:11786329211057352
31. Wong E, Backholer K, Gearon E, et al. Diabetes and risk of physical disability in adults: a systematic review and meta-analysis. Lancet Diabetes Endocrinol 2013;1:106–114
32. Nguyen A, Mui K. The staggering true cost of diabetes. April 2020. Accessed 1 March 2022. Available from https://www.grxstatic.com/4f3rgqwzdznj/6Q5qUjkrhppOzC9nM23vhW/867883e7208f529a8f24f1e7da67993e/Diabetes-Cost-White-Paper.pdf
33. Lentz R, Benson AB 3rd, Kircher S. Financial toxicity in cancer care: prevalence, causes, consequences, and reduction strategies. J Surg Oncol 2019;120:85–92
34. Mols F, Tomalin B, Pearce A, Kaambwa B, Koczwara B. Financial toxicity and employment status in cancer survivors. A systematic literature review. Support Care Cancer 2020;28:5693–5708
35. Fitch MI, Sharp L, Hanly P, Longo CJ. Experiencing financial toxicity associated with cancer in publicly funded healthcare systems: a systematic review of qualitative studies. J Cancer Surviv 2022;16:314–328
36. Berkowitz SA, Karter AJ, Corbie-Smith G, et al. Food insecurity, food "deserts," and glycemic control in patients with diabetes: a longitudinal analysis. Diabetes Care 2018;41:1188–1195