Published in final edited form as:

Arch Phys Med Rehabil. 2019 April ; 100(4 Suppl): S1–S12. doi:10.1016/j.apmr.2018.08.175.

The TBI-CareQOL Measurement System: Development and Preliminary Validation of Health-Related Quality of Life Measures for Caregivers of Civilians and Service Members/Veterans With Traumatic Brain Injury

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Abstract

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Objective: To develop a new measurement system, the Traumatic Brain Injury Caregiver Quality of Life (TBI-CareQOL), that can evaluate both general and caregiving-specific aspects of health-related quality of life (HRQOL) in caregivers of persons with traumatic brain injury (TBI).

Design: New item pools were developed and refined using literature reviews, qualitative data from focus groups, and cognitive debriefing with caregivers of civilians and service members/veterans with TBI, as well as expert review, reading level assessment, and translatability review; existing item banks and new item pools were assessed using an online data capture system. Exploratory and confirmatory factor analysis, item response theory, and differential item functioning analyses were utilized to develop new caregiver-specific item banks. Known-groups validity was examined using a series of independent samples t tests comparing caregivers of low-functioning vs high-functioning persons with TBI for each of the new measures, as well as for 10 existing Patient-Reported Outcomes Measurement Information System (PROMIS) measures.

Setting: Three TBI Model Systems rehabilitation hospitals, an academic medical center, and a military medical treatment facility.

Participants: Caregivers (N=560) of civilians (n=344) or service members/veterans with TBI (n=216).

Interventions: Not applicable.

Main Outcome Measures: The TBI-CareQOL measurement system (including 5 new measures and 10 existing PROMIS measures).

Results: Exploratory and confirmatory factor analysis, item response theory, and differential item functioning analyses supported the development of 5 new item banks for Feelings of Loss-Self, Feelings of Loss-Person with TBI, Caregiver-Specific Anxiety, Feeling Trapped, and Caregiver Strain. In support of validity, individuals who were caring for low-functioning persons with TBI had significantly worse HRQOL than caregivers that were caring for high-functioning persons with TBI for both the new caregiver-specific HRQOL measures, and for the 10 existing PROMIS measures.

Conclusions: The TBI-CareQOL includes both validated PROMIS measures and newly developed caregiver-specific measures. Together, these generic and specific measures provide a comprehensive assessment of HRQOL for caregivers of civilians and service members/veterans with TBI.

Keywords

Caregivers; Health care; Military personnel; Quality of life; Rehabilitation; Traumatic brain injuries; Veterans

Moderate to severe traumatic brain injury (TBI) often results in a variety of physical,¹⁻³ cognitive,⁴ emotional,^{5,6} and behavioral^{7,8} impairments. While the majority of individuals with TBI recover fully, those with more severe injuries can require long term care which typically involves informal caregivers (ie, family member or friend). These informal caregivers often report depression and anxiety,⁹⁻¹¹ disruption of family systems,⁹ decreased marital satisfaction and longevity,^{12,13} social isolation,^{10,14,15} increased need for mental health services,¹⁶ and increased use of alcohol and other drugs.^{16,17} In addition, these

caregivers report compromised health-related quality of life^{18–23} (HRQOL), a multidimensional construct reflecting physical, social, and emotional well-being.^{24,25} Assessing HRQOL in care-givers of persons with TBI is complicated by the lack of a gold standard assessment tool specific to this population. This is especially problematic because it impedes our ability to evaluate the impact that caregiving has on HRQOL and our ability to personalize treatment interventions to improve HRQOL and functioning for these individuals.

Caregiver studies often use HRQOL measures developed in other clinical populations and typically assess only a single domain (eg, depression or social support). Perhaps more significant is that measures of perceived burden borrowed from other caregiver populations, such as caregivers of individuals with dementia (eg, Zarit Burden Interview),²⁶ multiple sclerosis (eg, Caregiver Burden Scale),²⁷ or more generic caregiver HRQOL measures (Carer-QOL),²⁸ lack content coverage of TBI caregiver-specific issues and have unknown validity in caregivers of those with TBI.²⁹ Some researchers have elected to create new measures such as a self-reported measure of caregiver functioning¹¹ or a structured interview designed to assess caregiver HRQOL.³⁰ Unfortunately, the reliability, validity, and clinical utility of these measures are not well documented. Other measures, such as the Caregiver Burden Scale²⁷ and the Caregiver Burden Inventory³¹ measure only negative aspects of caregiving (eg, perceived burden). This is problematic given that assessing the positive aspects of caregiving is as important as assessing the negative.³² Similarly, generic scales of HRQOL such as the Medical Outcomes Study Short Form-36³³ or the Sickness Impact Profile³⁴ lack content coverage of TBI caregiver-specific issues.

Recently, a comprehensive system of HRQOL that can be used across different clinical conditions has been developed. The Patient-Reported Outcomes Measurement Information System (PROMIS)³⁵ includes generic measures of reliable and valid standardized patient-reported outcomes (PROs) that assess key symptoms and health concepts that are appropriate across diseases and conditions. PROMIS is unique as a system of HRQOL measures because it implements computerized adaptive test (CAT) technology, an item identification and delivery method whereby, after a standard first item is administered, each subsequently administered item is individually selected based on the previously administered item's response. CATs allow for sensitive measurement of a broad range of symptomatology with the administration of a small subset (generally between 4–6 items) of a domain's item bank, without losing the precision that is typically attained with a longer measure. Thus, CATs reduce participant response burden without sacrificing a measure's psychometric properties. In sum, CAT administration of measures has demonstrated better measurement precision and accompanying lower score-level-specific standard errors than comparative static measures, regardless of symptom severity, even when the number of items administered by a CAT and a static form are the same.³⁶ Despite the expansive scope of this innovative work, PROMIS was not conceptualized to examine HRQOL in any specific caregiving population.

Previous work in caregivers of civilians with TBI,²² as well as caregivers of service members/veterans (SMVs) with TBI,²¹ indicates that many of the PROMIS measures include relevant content. This includes problems with physical health (fatigue and sleep

difficulties), mental health (depression, anxiety, and anger), and social health (ability and participation in social activities as well as different kinds of social support. Gaps of measurement within the PROMIS framework for these caregivers were also identified. This includes anxiety specific to the caregiver role (concerns for re-injury; leaving the person alone), caregiver strain (burden; stress; feeling overwhelmed), grief/loss (regarding the future/potential of the care recipient, as well as the caregiver themselves), emotional suppression (putting on a brave face for others, even when things are not going well), and hypervigilance (controlling one's behavior/environment to prevent upsetting the person with the TBI).^{21,22} There were also areas where concerns for caregivers of civilians and SMVs diverged. For example, while financial concerns were discussed by both groups, caregivers of SMVs discussed concerns about caregiver stipend benefits (and fears about losing these benefits) whereas caregivers of civilians focused more on financial strain and loss of work.²¹ Furthermore, while both groups expressed feelings of anger, caregivers of SMVs expressed anger with barriers to health services (for care-givers and service members),³⁷ whereas caregivers of civilians expressed more generalized feelings of anger.²¹

While the PROMIS measurement system addresses many of these concerns, there are HRQOL domains that are relevant to these caregivers that are not currently represented. To address these shortcomings, the current study was designed to develop and validate a PRO measurement system, the Traumatic Brain Injury Caregiver Quality of Life (TBI-CareQOL), that captures both the generic and more unique aspects of HRQOL significant to care-givers of civilians and SMVs with TBI. We focused on validating relevant HRQOL domains from PROMIS and developing new measures that capture caregiver-specific HRQOL domains (using PROMIS measurement development standards³⁸). This report is complemented by several companion articles that provide a more in-depth examination of each of the domains highlighted in this paper.^{39–46}

Methods

Concept elicitation

Literature reviews and a qualitative focus group study were conducted to identify the HRQOL domains most relevant to care-givers of civilians²² and SMVs with TBI.²¹ This work identified HRQOL domains already represented by measures within the PROMIS system, and new HRQOL domains specific to caregivers of individuals with TBI. As indicated above, many similar concepts were identified for caregivers of civilians and SMVs with TBI.

Item development

The next step of the development of the TBI-CareQOL measurement system was to create preliminary item pools that assessed the domains of feelings of loss, feeling trapped, caregiver-specific anxiety, and caregiver strain. Each item pool went through several iterations of expert review, cognitive interviews with caregivers of civilians and caregivers of SMVs with TBI, reading level assessment, and translatability review (ie, to facilitate future translations into Spanish); see table 1. After initial item pool development, all items were reviewed and revised by an expert panel that included TBI clinicians and professionals,

clinical and research experts in caregivers of persons with TBI, and measurement development experts. Experts provided item content feedback with regard to item overlap, appropriateness of item content, wording refinements (ie, suggestions regarding phrasing and word substitutions), and item content coverage (ie, ensuring that all aspects of the specified domain were represented in the item pool and overall item pool content covered the full range of severity of the specified construct a TBI caregiver might experience). At least 5 caregivers reviewed each new item as part of the cognitive interview process. Cognitive interviews examined comprehension, processes used to arrive at particular responses (retrieving relevant information from memory, response selection practices including motivation and response bias), and overall relevance of an item to the content being measured.⁴⁷ Caregivers of civilians and caregivers of SMVs were represented in this cognitive interview process. Simultaneously, new items underwent a reading level assessment using the Lexile framework⁴⁸ to ensure that items were written with no higher than a fifth grade reading level so as to maximize each measure's utility among caregivers with low literacy. New items also underwent Spanish translatability review to maximize the potential for the future translation of these measures. Forward and backwards Spanish translatability was assessed by a Spanish-speaking translation scientist to identify potential concerns (eg, items containing idiomatic language; identification of wording or concepts that would be difficult to translate). Modifications that were made as a result of one of these reviews were again reviewed by at least 5 caregivers. After these reviews were complete, the expert review panel provided an additional round of edits that were reviewed (and approved) by previous cognitive interview respondents.

Given that it is common to lose as many as half of the items in an item pool during the development process and that we desired a minimum of 20 items in the final item bank (to sufficiently represent the full range of difficulty and discriminability for responses), we began each item pool with 75 items. This number accommodates a 25% loss during translatability, expert, cognitive, and literacy reviews, as well as an additional 50% loss of items during the quantitative study (described below). The final item pools (before the quantitative study) included 66 items for Care-giver Strain, 81 items for Caregiver-Specific Anxiety, 28 items for Feeling Trapped, and 98 items for Feelings of Loss.

Quantitative study

All final items were field tested with 560 caregivers of individuals with TBI (n=344 caregivers of civilians with TBI; n=216 caregivers of SMVs with TBI) according to measurement standards established by PROMIS investigators to develop new item banks capable of being administered by CATs.⁴⁹

Participants—Caregivers of civilians with TBI were recruited by the Kessler Foundation (West Orange, NJ), Rehabilitation Institute of Michigan (Detroit, MI), TIRR Memorial Hermann (Houston, TX), and University of Michigan (Ann Arbor, MI). Recruitment for these caregivers utilized affiliated treatment centers, existing TBI care-giver databases, as well as medical record data capture systems⁵⁰ and community outreach efforts. Caregivers of SMVs with TBI were recruited through hospital-based and community outreach efforts at

Walter Reed National Military Medical Center and through community-based outreach at the University of Michigan.

For both groups, caregivers were at least 18 years old, were able to read and understand English, and were caring for an individual with a medically documented TBI that was sustained after age 15. All caregivers were required to provide physical assistance, financial assistance, or emotional support to an individual with a TBI. Inclusion criteria for caregivers of civilians with TBI required caring for an individual that was at least 1 year post a medically documented complicated mild, moderate, or severe TBI, based on TBI Model Systems criteria.⁵¹ Inclusion criteria for caregivers of SMVs with TBI required caring for an individual who had sustained a TBI that was medically verified by a Department of Defense or Department of Veteran Affairs treatment facility at least 1 year prior to study participation. For both groups, caregivers were required to be providing assistance to an individual with TBI. Caregivers of SMVs with TBI were also asked an additional eligibility question: “On a scale of 0–10, where 0 is no assistance and 10 is assistance with all activities, how much assistance does the person you care for require from you to complete activities of daily living due to problems resulting from his/her TBI? Activities could consist of personal hygiene, dressing and undressing, housework, taking medications, managing money, running errands, shopping for groceries or clothing, transportation, meal preparation and cleanup, remembering things, etc.” Care-givers of SMVs with TBI were eligible if they indicated a response of ≥ 1 . Data were collected with the approval of institutional review boards at each site, and participants provided consent prior to participation.

Measures

TBI-CareQOL Item Pools.: The Caregiver Strain item pool captured feelings of being overwhelmed, stressed, defeated, downtrodden, and beaten-down as a result of the caregiver role. The Caregiver-Specific Anxiety item pool captured feelings of worry and anxiety specific to general safety, health, and future well-being of the person with the injury. The Feeling Trapped item pool captured feelings of being unable to go places or do things due to caregiving responsibilities. Finally, the Feelings of Loss item pool captured feelings of sorrow, mental suffering, or distress over changes related to the TBI.

PROMIS Measures.^{35,52} Participants also completed 10 measures from PROMIS. This included depression (feelings of sadness and worthlessness), anxiety (fear, anxiety, and hyper-arousal), anger (irritability and frustration), ability to participate in social roles and activities (SRA) (involvement in one’s usual social roles and activities), satisfaction with SRA (satisfaction in one’s usual social roles and activities), emotional support (feelings of being cared for and having supportive relationships), informational support (ability to access people with helpful information and advice), social isolation (feelings of being emotionally cut off from other people), fatigue (feelings of tiredness and exhaustion related to being overwhelmed), and sleep disturbance (sleep quality, depth, and restorative sleep). All participants completed these measures as CATs and computer-based static short forms (SFs). We examined scores on the CAT administrations in this report. Item response theory-based scores for all 10 of the measures were standardized using T scores (mean $\pm$ SD 50 $\pm$ 10); higher scores indicate more of the trait being measured. Thus, for negative traits (eg,

depression, anxiety, anger, social isolation, fatigue, sleep disturbance), higher scores indicate worse HRQOL, whereas for positive traits (ie, ability to participate in SRA, satisfaction with SRA, emotional support, and informational support) higher scores indicate better HRQOL.

Functional Ability of the Care-Recipient.: The Mayo-Portland Adaptability Inventory Fourth Edition (MPAI-4)⁵³ was administered to obtain an estimate of functional ability following TBI. This 35-item measure assesses the caregivers' perceptions of the overall functional ability of the person with the TBI. MPAI-4 scores are represented as T scores (mean $\pm$ SD 50 ± 10) with higher scores indicating lower functional ability. We divided the participants into 2 groups according to recommended cutoffs provided in the MPAI-4 manual⁵⁴: caregivers with scores less than 60 were classified as caring for someone who was high functioning, and caregivers with scores greater than or equal to 60 were classified as caring for someone who was low functioning. Reliability for this measure has been established in caregivers of persons with TBI.^{55–59}

Data capture—PROs were completed through Assessment Center (<https://www.assessmentcenter.net>), either at a designated computer at the site, or on a personal or publically available computer with an internet connection. Study participants typically completed the survey within a 2-week time frame.

Analysis Plan.: Descriptive statistics are provided for both the civilian and SMV samples. Medical record confirmation was only consistently available for caregivers of civilians; while TBI severity data was available for caregivers of SMVs recruited through Walter Reed National Military Medical Center, these data were missing for the majority of the caregivers recruited through the University of Michigan. In order to better understand and characterize the different samples that comprised the calibration sample, independent sample *t* tests were used to identify group differences between caregivers of civilians and caregivers of SMVs for caregiver age, years in the caregiver role, and age of the person with the TBI. Chi-square analyses were used to identify group differences in sex (men vs women), race (white vs black), ethnicity (Hispanic vs non-Hispanic), education (high school graduate or less, some college, or college graduate), marital status (married/cohabiting vs all other groups), and sex of the person with the TBI (men vs women). Fisher's exact test^{60,61} was used to examine group differences for relationship status (parent vs spouse vs child/other family member, vs other).

Development of the new HRQOL item banks included a combination of classical test theory and item response theory (IRT) analytical approaches. Classical test theory assumes that each item has equal weight in determining an overall score; it typically requires the successful completion of all test items in order to estimate an individual's true score.⁶² Scoring algorithms do exist to deal with permissible levels of item response missingness (eg, scoring might be allowed for persons responding to 50% or more of a measure's items); however, these algorithms rely on response imputation (eg, using the average items for which there are responses to obtain a total score or using the average item response as the replacement value for missing individual item responses). This can be contrasted with IRT, where each individual item is calibrated, its unique contribution to scoring is known, and it can be used by itself or in conjunction with other individual items to estimate an individual's

true score. IRT offers several advantages for PRO development.^{35,52} First, IRT provides detailed information about both the discriminability and difficulty of each individual item for a given measure; this allows for the retention of only the best performing items for a given population. IRT analysis results can also be used to program CAT administration for a PRO measure.

Our analytical process involved identifying a unidimensional item pool (using exploratory and confirmatory factor analysis [EFA; CFA]) and conducting IRT^a analyses on each unidimensional item pool to establish the item calibration data (ie, item parameters) needed to program a CAT. Each item pool was analyzed separately. Items with sparse cells (ie, having response categories with $n < 10$ respondents) were excluded,^{63,64} as were items whose item-adjusted total score correlation was < 0.40 .⁶³ Items were checked for monotonicity (ie, as each individual item's score increases in magnitude, so should the overall total score [excluding the item being tested for monotonicity]) using item-rest plots produced using a nonparametric IRT model (TestGraf).^b Given the large amount of missing data for TBI severity among SMVs with TBI, all planned EFA and CFA analyses were initially conducted using all caregivers, regardless of whether or not documentation was provided for the TBI severity of the care recipient; these analyses were then reconducted using only those with full medical record documentation (which included documentation for TBI severity). These analyses were undertaken at the full-sample level as well as at the civilian-only and SMV-only sample levels. Full-sample EFAs and CFAs were conducted using Mplus (version 7.4).^c EFAs were used to establish initial evidence of essential unidimensionality, using, for example, the ratio of eigenvalue 1 to eigenvalue 2 > 4 as a criterion. CFAs were then used to iteratively screen for low factor loadings ($\lambda < 0.50$) and local dependence (residual correlation > 0.20 ; correlated error modification index > 100); individual items were deleted/added back and models were rerun multiple times to identify the best fit. Final item set CFA models were then run to assess overall model fit, using standard fit criteria (confirmatory fit index, Tucker-Lewis index, root mean squared error of approximation [RMSEA], and Standardized Root Mean Square Residual). An iterative process was employed throughout these analyses, and clinical input was taken into account at item content decision junctures to finalize item exclusion/inclusion.^{65–67} Given that analyses demonstrated that there were no differences between participants with and without documented injury severity with regard to explored and confirmed item pool dimensionality, we report findings for the full sample below.

Once unidimensional item pools were identified, an IRT graded response model⁶⁸ was fit to the data, using IRTPRO (version 3.1).^d To be retained in these analyses, items had to demonstrate expected psychometric properties; items displaying significant item misfit (S-X2 item fit index, $P < .01$) were excluded. Items were also examined for differential item functioning (DIF) based on age (≥ 40 , $n=346$ vs < 40 , $n=212$), education ($< \text{college}$, $n=271$ vs $\geq \text{college}$, $n=288$), and status (caregiver of civilian, $n=344$ vs caregiver of SMV, $n=216$); the

^a.PARSCALE; Scientific Software International Inc.

^b.TestGraf; McGill University.

^c.Mplus; Muthén & Muthén.

^d.IRTPRO for Windows; Scientific Software International Inc.

R package LORDIF (version 0.3–2)^e was used to conduct these analyses.⁶⁹ DIF is an indication of unexpected, potentially biasing, item performance (eg, do men at a specific trait level report higher positive responses for a particular item than do women at the same specific trait level?). Items exhibiting impactful DIF (ie, Nagelkerke pseudo- R^2 change 0.20 and >2% of DIF-corrected vs uncorrected score differences exceeding uncorrected score standard errors) for age, education, or civilian vs SMV status were excluded from the final item set. The aggregate results for these analyses are summarized below; detailed analyses for each individual item pool are highlighted elsewhere.^{41–44}

Preliminary Validation of TBI-CareQOL and PROMIS Measures in

Caregivers.: Independent *t* tests were used to compare each TBI-CareQOL and PROMIS CAT between caregivers of low- and high-functioning individuals (defined using MPAI-4 scores). Simulated CAT scores (using Firestar70,^f and IRTPRO software) were examined for each of the TBI-CareQOL measures (items were administered until estimated SE was 3; a minimum of 4 and a maximum of 12 items were administered). We hypothesized that caregivers of individuals who were high functioning would report better HRQOL than caregivers of individuals who were low functioning.

Sample Size Considerations.: Sample size requirements were based on the power needed for conducting IRT analyses, the primary analytic method in the current effort. While sample sizes of 200–1000 have been proposed when using a graded response model, in which a larger sample size can produce more stable parameter estimation,^{68,71} rules of thumb dictate that a minimum of 5–10 individuals are needed for every item within an item pool.^{72–74} Given that our largest item pool included 98 items, we would need 490 individuals for reliable IRT item parameter estimation. Additionally, DIF analyses can be performed provided the overall sample size is at least 500 and there are at least 200 participants within each variable category tested (balanced subgroups are not required).⁷⁵ If an item was flagged for DIF, unique group-specific item parameters would be estimated for the item in question. Sample size requirements assured that group-specific item parameter estimates would be robust. For DIF analyses, we tested 3 factors: age (≥ 40 , $n=346$ vs <40 , $n=212$), education ($< \text{college}$, $n=271$ vs $\geq \text{college}$, $n=288$), and caregiver-type (civilian, $n=344$, vs SMV, $n=216$).⁷⁵ In order to determine if generational differences might lead to item performance differences, a cutoff of 40 years of age was selected to represent younger (ie, participants <40 y of age) vs older study participants (ie, participants ≥ 40 y of age).

Results

Participant demographics

Demographic data for both the civilian and SMV samples are provided in table 2.

^eR; R Foundation for Statistical Computing.

^fFirestar; Choi.

New TBI-CareQOL item bank and CAT development

Across the item pools, 273 items were field tested. EFA and CFA supported 40 items for the Caregiver Strain item pool, 31 items for the Caregiver-Specific Anxiety item pool, and 16 items for the Feeling Trapped item pool. Finally, for the Feelings of Loss item pool, EFA and CFA supported 2 unidimensional item pools: Feelings of Loss-Self (43 items) and Feelings of Loss-Person with TBI (20 items). Feelings of Loss-Self examines feelings of loss related to the caregivers' own occupation, physical well-being, interpersonal relationships, recreational activities, future plans, and sense of personal identity and Feelings of Loss-Person with TBI examines the caregiver's feelings of loss about the person with the TBI's previous abilities and future potential, as well as changes personality changes. The final number of items for each item bank and the analysis results for the new TBI-CareQOL measures are reported in table 3. Detailed analyses for the development of the final item banks are reported elsewhere.^{22,41–44} Five new CATs were developed: Caregiver Strain, Caregiver-Specific Anxiety, Feeling Trapped, Feelings of Loss-Self, and Feelings of Loss-Person with TBI. Six-item SFs were developed by expert review (item content-based and psychometric quality-based) for each of these measures. Average participant administration time for each new TBI-CareQOL SF was less than 1 minute.

Scoring

All newly developed TBI-CareQOL measures are presented as T scores (mean $\pm$ SD 50 $\pm$ 10), which is the same metric utilized in PROMIS.⁷⁶ Note that the reference group (ie, the group used to develop the algorithm for the CATs) for the new measures is TBI caregivers, while the reference group for the PROMIS measures is the general population.

Preliminary validation of the TBI-CareQOL measures in caregivers

There were significant differences between caregivers who cared for individuals with high vs low functioning on all of the TBI-CareQOL and PROMIS measures (table 4); differences were in the expected direction. Specifically, compared to caregivers of high-functioning individuals (n=402), caregivers of low-functioning individuals (n=144) had significantly higher scores on all 5 TBI Care-QOL measures, indicating that they had poorer HRQOL (more feelings of being trapped, more feelings of loss, greater caregiver strain, and more caregiver-specific anxiety) than those who were caring for high-functioning individuals.

Preliminary validation of PROMIS measures in caregivers

There were significant differences between caregivers of high- and low-functioning individuals for each of the PROMIS measures (see table 4). Again, caregivers of individuals with lower functioning reported worse HRQOL than caregivers of those with higher functioning. Specifically, caregivers of lower-functioning individuals reported more anger, anxiety, depression, social isolation, fatigue, and sleep disturbance, as well as less emotional and informational support, and less participation in and satisfaction with SRA than those caring for high-functioning individuals.

Discussion

The TBI-CareQOL measurement system was developed using state-of-the-science measurement development standards to capture the unique experiences of caregivers who support persons with TBI.³⁸ The TBI-CareQOL currently includes 10 validated PROMIS measures, as well as 5 new TBI-caregiver-specific measures: Caregiver Strain, Caregiver-Specific Anxiety, Feeling Trapped, Feelings of Loss-Self, and Feelings of Loss-Person with TBI. The TBI-CareQOL capitalizes upon previous measure development work by incorporating relevant, generic measures from PROMIS, alongside TBI-caregiver-specific aspects of HRQOL. Scores from the PROMIS measures could be used to make cross-population comparisons (eg, comparisons across different types of caregivers or clinical populations). The TBI-CareQOL also offers a brief and more comprehensive assessment of HRQOL and caregiving-specific functioning than existing caregiver or generic HRQOL assessments. Also, the TBI-CareQOL is also the first PRO assessment for caregivers that utilizes item banking and CAT methodology. Given the demands on those who are providing care, this type of test administration caters to their unique needs but is also sensitive to their time limitations and potential fatigue.

All measures within this system are scored according to a T distribution with a mean of 50 and SD of 10; scores between 40 and 60 can generally be considered in the normal range.⁷⁶ Scores that are above 60 for negative concepts and below 40 for positive concepts are indicative of clinically significant impairment (as only 16% of the population will have scores reflecting impairment).⁷⁷ Scores below 40 ± 1.0 for positive concepts (eg, emotional support) and above 60 for negative concepts (eg, anger) can be considered to represent poor HRQOL. Similarly, scores above 60 for positively worded concepts and below 40 for negatively worded concepts can be considered to represent good HRQOL. Scores indicating significant impairment can be used to identify caregivers who may benefit from appropriate services/referrals.

From a clinical standpoint, this measure is the first HRQOL assessment with items unique to caregivers of those with TBI. Family, friends, and other important support persons can be affected by caring for an individual with a TBI; thus, it is just as important to provide recommendations for these caregivers as it is for the person with TBI. This is especially important given that the HRQOL of the caregiver has a direct impact on the health and function of the person with the TBI.^{78–85} TBI-CareQOL measures could be implemented in postacute rehabilitation settings and used to guide education and psychotherapy recommendations for the caregiver. Given the fact that these measures tap multiple aspects of HRQOL, they could be used for fine-tuned interventions that are targeted toward specific problems faced by caregivers, as identified by responses to individual item banks (eg, Caregiver-Related Anxiety). The brevity of the scales facilitates rapid serial administration of several measures in a short period of time.

Study limitations

There are several limitations to this study. Medical record documentation was not always clear regarding injury severity. Specifically, while 95% of the caregivers of civilians with

TBI and 40% of the caregivers of SMVs with TBI had sufficient medical record documentation to characterize both TBI occurrence and severity, 26% of the overall sample did not have enough documentation to characterize TBI severity due to difficulties securing military medical records for caregivers recruited through community outreach at the University of Michigan. In addition, the SMV eligibility question about assistance was not validated and its utility is unknown. The majority of the surveys were completed at home; thus, it is possible that some participant answers were influenced by another individual or may have even been completed by someone other than the specified caregiver. Also, although translatability reviews were conducted, perceptions related to idiomatic language and wording/concepts that would be difficult to translate were made by a sole expert (and for a single language), rather than a consensus approach.

Conclusions

Findings from this study provide preliminary reliability and validity data that support the clinical utility of these measures in caregivers of civilians and SMVs with TBI. This measurement system should provide an efficient assessment tool for sensitively evaluating HRQOL in caregivers and can be used to evaluate behavioral interventions focused on improving HRQOL for these individuals. Future work is needed to examine the relative contribution of each of these different aspects of HRQOL to the overall functioning of these caregivers, as well as to examine how different demographic variables (eg, sex, race, ethnicity, age) are related with HRQOL as measured by the TBI-CareQOL. TBI-CareQOL CATs and SFs will be available through www.assessmentcenter.net. TBI-CareQOL SFs will also be available through the TBI-CareQOL website (<http://www.tbicareqol.com>).

Acknowledgments

We thank the investigators, coordinators, and research associates/assistants who worked on this study, the study participants, and organizations who supported recruitment efforts. The University of Michigan Research Team would also like to thank the Hearts of Valor and the Brain Injury Association of Michigan for assistance with community outreach for recruitment efforts at this site.

TBI-CareQOL site investigators and coordinators: Noelle Carlozzi, Anna Kratz, Amy Austin, Mitchell Belanger, Micah Warschausky, Siera Goodnight, Jennifer Miner (University of Michigan, Ann Arbor, MI); Angelle Sander (Baylor College of Medicine and TIRR Memorial Hermann, Houston, TX); Curtisa Light (TIRR Memorial Hermann, Houston, TX); Robin Hanks, Daniela Ristova-Trendov (Wayne State University/Rehabilitation Institute of Michigan, Detroit, MI); Nancy Chiaravalloti, Dennis Tirri, Belinda Washington (Kessler Foundation, West Orange, NJ); Tracey Brickell, Rael Lange, Louis French, Rachel Gartner, Megan Wright, Angela Driscoll, Diana Nora, Jamie Sullivan, Nicole Varbedian, Johanna Smith, Lauren Johnson, Heidi Mahatan, Mikelle Mooney, Mallory Frazier, Zoe Li, and Deanna Pruitt (Walter Reed National Military Medical Center/Defense and Veterans Brain Injury Center, Bethesda, MD).

Supported by the National Institutes of Health National Institute of Nursing Research (grant no. R01NR013658), the National Center for Advancing Translational Sciences (grant no. UL1TR000433), and the Defense and Veterans Brain Injury Center.

List of abbreviations:

CAT	computer adaptive test
CFA	confirmatory factor analysis
DIF	differential item functioning

EFA	exploratory factor analysis
HRQOL	Health-Related Quality of Life
IRT	item response theory
MPAI-4	Mayo-Portland Ability Inventory, Fourth Edition
PRO	patient-reported outcome
PROMIS	Patient-Reported Outcomes Measurement Information System
RMSEA	root mean squared error of approximation
SF	short form
SMV	service member/veteran
SRA	social roles and activities
TBI	traumatic brain injury
TBI-CareQOL	Traumatic Brain Injury Caregiver Quality of Life

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Table 1

Iterative item development process for new TBI-CareQOL PROs

Domain	Item Pool Total Items	Expert Review (no. deleted, no. added, no. revised) Total Items	Expert Review (no. deleted, no. added, no. revised) Total Items	Cognitive Interviews (no. deleted, no. added, no. revised) Total Items	Translation Review (no. deleted, no. added, no. revised) Total Items	Literacy Review (no. deleted, no. added, no. revised) Total Items	Consensus Meeting (no. deleted, no. added, no. revised) Total Items	Cognitive Interviews (no. deleted, no. added, no. revised) Total Items	Final No. of Items
Caregiver Strain	75 items	(16, 8, 0) 67 items	(13, 28, 0) 82 items	(6, 0, 1) 76 items	(10, 0, 39) 66 items	(0, 0, 0) 66 items	(0, 0, 2) 66 items	(0, 0, 0) 66 items	66 items
Caregiver-Specific Anxiety	75 items	(39, 36, 0) 72 items	(18, 28, 0) 82 items	(0, 18, 0) 100 items	(19, 0, 50) 81 items	(0, 0, 0) 81 items	(0, 0, 8) 81 items	(0, 0, 0) 81 items	81 items
Feeling Trapped	75 items	(50, 0, 0) 25 items	(1, 9, 0) 33 items	(5, 0, 1) 28 items	(0, 0, 15) 28 items	(0, 0, 0) 28 items	(0, 0, 0) 28 items	(0, 0, 0) 28 items	28 items
Feelings of Loss	75 items	(14, 11, 0) 72 items	(1, 60, 0) 131 items	(4, 0, 14) 127 items	(29, 0, 75) 98 items	(0, 0, 0) 98 items	(0, 0, 2) 98 items	(0, 0, 0) 98 items	98 items

Table 2

Demographic data for the TBI-CareQOL participants

Variable	Caregivers of Civilian TBI (n = 344)	Caregivers of Military TBI (n = 216)	Combined Caregiver Sample (N = 560)	Statistical Test to Identify Group Differences (Effect Size)
Age (y)				
Mean ± SD	51.6±14.0	37.2±8.6	46.1±14.1	$t(555.94) = 15.04, P < .01 (d = 1.24)$
Sex (%)				
Women	78.0	98.1	85.5	$\chi^2(1) = 44.74, P < .01 (V = .28)$
Men	22.0	1.9	14.5	
Ethnicity (%)				
Not Hispanic or Latino	86.3	88.8	87.3	$\chi^2(1) = 1.27, P = .26 (V = .05)$
Hispanic or Latino	11.9	8.4	10.6	
Not provided	1.7	2.8	2.2	
Race (%)				
White	71.8	85.5	77.2	$\chi^2(2) = 33.05, P < .01 (V = .26)$
African American	20.3	3.3	13.8	
Other	7.6	11.2	8.8	
Unknown	0.3	0.0	0.2	
Education (%) [*]				
High school graduate or less	27.1	4.7	18.6	$\chi^2(2) = 46.33, P < .01 (V = .28)$
Some college	35.3	52.8	42.0	
College graduate	37.6	42.5	39.5	
Marital status (%) [*]				
Single, never married	17.5	1.4	11.3	$\chi^2(1) = 37.74, P < .01 (V = .39)$
Married/cohabitating	60.5	96.3	74.2	
Separated/divorced	14.8	1.9	9.9	
Widowed	6.1	0.5	3.9	
Unknown	1.2	0.0	0.7	
Years in caregiver role				
Mean ± SD	5.9±6.5	5.6±3.0	5.8±5.4	$t(513.24) = .71, P = .48 (d = .06)$
Relationship to person with TBI (%) [*]				

Variable	Caregivers of Civilian TBI (n = 344)	Caregivers of Military TBI (n = 216)	Combined Caregiver Sample (N = 560)	Statistical Test to Identify Group Differences (Effect Size)
Spouse	36.6	93	58.2	Fisher exact test = 201.00, $P < .001$ ($V = .39$)
Parent	35.8	2.3	22.9	
Child/other family member	19.2	2.8	12.9	
Other (eg, friend)	8.4	1.9	5.9	
Age of person with TBI				
Mean $\pm$ SD) = Sex of person with TBI (%)	42.3 $\pm$ 14.6	37.1 $\pm$ 7.5	40.3 $\pm$ 12.6	$t(535.41) = 5.56$, $P < .001$ ($d = .45$)
Men	74.7	99.5	84.2	$\chi^2(1) = 61.20$, $P < .001$ ($V = .33$)
Women	25.3	0.5	15.8	
Time since injury				
Mean $\pm$ SD	6.9 $\pm$ 5.6	8.7 $\pm$ 4.0	7.6 $\pm$ 5.1	$t(533.49) = 4.40$, $P < .001$ ($d = .37$)
TBI severity [†] (%)				
Mild	NA	19.2		
Complicated mild	17.7	1.9		
Equivocal mild	NA	15.4		
Moderate	20.9	2.3		
Severe	56.1	1.9		
Penetrating	NA	1.4		
Unknown	5.2	57.9 [‡]		
Mechanism of injury (%)				
MVA	53.8	3.7	34.5	
Falls	16.1	3.3	11.1	
Struck by an object or thrown against an object	1.2	4.2	2.3	
Gunshot or assault	15.2	2.3	10.3	
Other accidents (eg, bicycle accident, pedestrian struck by motor vehicle)	9.6	0.0	5.9	
Sports-related TBI	1.7	0.0	1.1	
Multiple modes/other/unknown	2.4	7.0	4.1	
Blast-related injury	NA	79.4	30.6	
Deployment-related (%)	NA	88.0		
Military service branch (%)	NA			
Army	NA	58.9		

Variable	Caregivers of Civilian TBI (n = 344)	Caregivers of Military TBI (n = 216)	Combined Caregiver Sample (N = 560)	Statistical Test to Identify Group Differences (Effect Size)
Marine Corps	NA	17.3		
Army National Guard	NA	9.3		
Navy	NA	4.7		
Air Force	NA	3.3		
Air National Guard	NA	1.9		
Reserves (all branches)	NA	4.2		
Coast Guard	NA	0.5		

* Entries in the table represent percentage of participants unless otherwise specified.

[‡] Documentation of TBI severity was different for the 2 groups; for the civilian sample, TBI severity was determined according to TBI model system criteria,⁵¹ whereas for the military sample, TBI severity was determined according to Department of Defense criteria.⁸⁶

[‡] Documentation of TBI severity was unavailable for the vast majority of the military sample collected through community outreach by the University of Michigan. Abbreviation: NA, not applicable.

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Table 3

New TBI-CareQOL measures statistics

Domain	Final Items	Items in SF	Item(s) Removed Due to IRT-Based Item Misfit	CFI (.95)	TL (.95)	CFA-Based RMSEA (<.15)	Cronbach's Alpha for Item Bank (>0.80)	IRT-Based RMSEA (<.15)	Response Pattern Reliability	Slope Range	Threshold Range	Mean SF Administration Time in Seconds (Mean Administration Time per Item)
Caregiver Strain	33	6	7	.95	.95	.096	.98	.08	.98	1.42/3.72	-1.32/3.17	42 (7)
Caregiver-Specific Anxiety	27	6	4	.95	.95	.10	.97	.05	.97	1.05/4.55	-1.67/2.54	39 (6)
Feeling Trapped	15	6	1	.98	.97	.14	.97	.05	.93	2.24/4.83	-0.47/1.94	41 (7)
Feelings of Loss—Self	30	6	13	.96	.96	.10	.98	.09	.97	2.00/3.92	-1.45/2.30	42 (7)
Feelings of Loss—Person with TBI	19	6	1	.97	.97	.095	.96	.09	.96	1.53/3.70	-1.92/2.12	49 (8)

Abbreviations: CFI, confirmatory fit index; TLI, Tucker-Lewis index.

Table 4
Preliminary validation of TBI-CareQOL and PROMIS measures in caregivers of individuals with TBI

TBI-CareQOL	High (MPAI-4<60) n = 402		Low (MPAI-4 60) n = 144		PROMIS (CAT)	d	t	High (MPAI-4<60) n = 402		Low (MPAI-4 60) n = 144		t	d
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD				Mean ± SD	Mean ± SD				
Feeling Trapped CAT	47.02±8.73	58.39±6.57	16.25 *	1.47	Anger			51.77±9.90	57.52±8.61	6.57 *	0.62		
Feeling Trapped SF	46.66±8.25	59.44±8.34	15.90 *	1.54	Anxiety			53.04±9.24	59.46±8.59	7.26 *	0.72		
Feelings of Loss—Self CAT	47.81±9.05	56.37±7.86	10.75 *	1.01	Depression			50.40±9.39	56.35±9.41	6.49 *	0.63		
Feelings of Loss—Self SF	47.36±8.77	57.33±9.54	11.44 *	1.09	Emotional Support			49.16±8.94	45.58±9.82	3.82 *	0.38		
Feelings of Loss—Person with TBI CAT	48.15±9.37	55.01±8.02	7.82 *	0.79	Informational Support			49.94±10.31	46.54 ±10.27	3.38 *	0.33		
Feelings of Loss—Person with TBI SF	48.01±9.57	55.50±9.07	8.17 *	0.80	Ability to Participate in SRA			51.46±9.04	42.96 ±8.67	9.74 *	0.96		
Caregiver Strain CAT	47.89±9.25	55.87±8.34	9.11 *	0.91	Satisfaction with SRA			47.78±8.72	41.28 ±7.41	8.57 *	0.80		
Caregiver Strain SF	47.86±9.38	55.75±9.30	8.68 *	0.84	Social Isolation			48.20±9.29	56.42 ±9.16	9.11 *	0.89		
Caregiver-Specific Anxiety CAT	47.81±8.98	56.38±8.60	9.93 *	0.97	Fatigue			52.46±9.48	59.28±9.42	7.39 *	0.72		
Caregiver-Specific Anxiety SF	47.42±8.77	57.11±9.57	11.09 *	1.06	Sleep Disturbance			52.13±9.65	58.91±9.49	7.23 *	0.71		

* All comparisons significant at $P<.001$.