Epilepsia Open® The Open Access Journal of the International League Against Epilepsy

Open Access

FULL-LENGTH ORIGINAL RESEARCH

# Single-item measure for assessing quality of life in children with drug-resistant epilepsy

*†Lauryn Conway, ‡§Elysa Widjaja, and *†‡Mary Lou Smith

*Epilepsia Open*, 3(1):46–54, 2018
doi: 10.1002/epi4.12088

**Lauryn Conway** is a doctoral candidate in the Department of Psychology at the University of Toronto.

## Summary

**Objective:** **The current study investigated the psychometric properties of a single-item quality of life (QOL) measure, the Global Quality of Life in Childhood Epilepsy question (G-QOLCE), in children with drug-resistant epilepsy.**

**Method:** **Data came from the Impact of Pediatric Epilepsy Surgery on Health-Related Quality of Life Study (PESQOL), a multicenter prospective cohort study (n = 118) with observations collected at baseline and at 6 months of follow-up on children aged 4–18 years. QOL was measured with the QOLCE-76 and KIDSCREEN-27. The G-QOLCE was an overall QOL question derived from the QOLCE-76. Construct validity and reliability were assessed with Spearman's correlation and intraclass correlation coefficient (ICC). Responsiveness was examined through distribution-based and anchor-based methods.**

**Results:** **The G-QOLCE showed moderate ($r \geq 0.30$) to strong ($r \geq 0.50$) correlations with composite scores, and most subscales of the QOLCE-76 and KIDSCREEN-27 at baseline and 6-month follow-up. The G-QOLCE had moderate test-retest reliability (ICC range: 0.49–0.72) and was able to detect clinically important change in patients' QOL (standardized response mean: 0.38; probability of change: 0.65; Guyatt's responsiveness statistics: 0.62 and 0.78). Caregiver anxiety and family functioning contributed most strongly to G-QOLCE scores over time.**

**Significance:** **Results offer promising preliminary evidence regarding the validity, reliability, and responsiveness of the proposed single-item QOL measure. The G-QOLCE is a potentially useful tool that can be feasibly administered in a busy clinical setting to evaluate clinical status and impact of treatment outcomes in pediatric epilepsy.**

**KEY WORDS:** **Quality of life, Reliability, Validity, Pediatric epilepsy.**

Considerable effort has been devoted to developing psychometrically robust measures of quality of life (QOL) in pediatric epilepsy.[1–4] One of the most widely used, epilepsy-specific measures of QOL for children with epilepsy is the Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-76), a 76-item, parent-rated instrument.[1] Despite its prolific use, the QOLCE-76 has a relatively large number of items, which prompted the development of the QOLCE-55, a shortened version with enhanced internal consistency and a sound factor structure.[3]

While the QOLCE-55 reduces response burden in both cost- and time-intensive clinical research settings, there remains a pressing need for practical measures of QOL that can be used by neurologists and other health practitioners to monitor treatment progress of patients. Clinicians are only likely to use patient-reported QOL measures if the tools are meaningful, psychometrically sound, and easy to implement in daily practice.[5] Given that fiscal pressures in many tertiary care settings have reduced clinicians' contact time with patients, the availability of brief QOL measures that can be

Accepted November 6, 2017.

*Department of Psychology, Hospital for Sick Children, Toronto, Ontario, Canada; †Department of Psychology, University of Toronto Mississauga, Mississauga, Ontario, Canada; ‡Division of Neurology, Hospital for Sick Children, Toronto, Ontario, Canada; and §Diagnostic Imaging, Hospital for Sick Children, Toronto, Ontario, Canada

Address correspondence to Mary Lou Smith, Department of Psychology, University of Toronto Mississauga, 3359 Mississauga Road North, Mississauga, ON L5L 1C6, Canada. E-mail: marylou.smith@utoronto.ca

## Key Points

- The current study examined the psychometric properties of a single-item quality of life measure, the Global Quality of Life in Childhood Epilepsy questionnaire (G-QOLCE), in children with drug-resistant epilepsy
- Results offer preliminary evidence regarding the validity, reliability, and responsiveness of the G-QOLCE, suggesting that it is a potentially useful tool that can provide meaningful information to neurologists and other health practitioners
- Future research is needed to validate the G-QOLCE across different populations of children with epilepsy

feasibly administered during a busy clinic visit is imperative.[6]

The current study investigated the psychometric properties of a single-item QOL measure, the Global Quality of Life in Childhood Epilepsy questionnaire (G-QOLCE), which asks about the child's QOL in the past 4 weeks. We assessed the validity, reliability, and responsiveness of the G-QOLCE using a multicenter sample of children with drug-resistant epilepsy. As a secondary aim, we examined potential clinical and psychosocial correlates (identified in prior studies[7,8]) of G-QOLCE scores at baseline and 6-month follow-up. The use of a more clinically severe, drug-resistant sample for initial psychometric evaluation of the G-QOLCE is supported by previous work examining the benefits of patient-reported health status measurement in clinical practice.[9] Specifically, neurologists found the routine use of health status assessment to be more beneficial for patients with lower subjective health.

## Methods

### Participants

Data were collected as part of the Impact of Pediatric Epilepsy Surgery on Health-Related Quality of Life Study (PEPSQOL), a multicenter longitudinal prospective cohort study.[7] Participants were recruited between April 2014 and September 2016 while being evaluated for epilepsy surgery at eight centers across Canada. Patients with drug-resistant, localization-related epilepsy (assessed by clinical semiology and/or electroencephalography) age 4–18 years were eligible for inclusion in the study. Drug-resistant epilepsy was defined as clear documentation of failure to obtain seizure control after trials of at least two AEDs, and was confirmed by the child's treating specialist in epilepsy (neurologist/epileptologist). Exclusion criteria included inability to complete the questionnaires (e.g., non-English-speaking caregivers); prior resective surgery, past or planned nonresective (e.g., corpus callostomy) epilepsy surgery, or vagal nerve stimulator placement; and neurometabolic disorders, neurodegenerative disorders, genetic epilepsy syndromes such as genetic generalized epilepsy, and epileptic encephalopathies.

The current study utilized data from 118 children assessed at two time points. At baseline, patients were either in the process of undergoing or had undergone a presurgical evaluation. At 6-month follow-up, approximately 32% of children had undergone surgery, while 68% had not had surgery, either because they were still undergoing evaluations, were deemed ineligible for surgery, or did not proceed with surgery owing to potential neurological deficit with surgery. All participants were treated with antiepileptic drugs (AEDs) at both times points. Overall, 226 participants were approached for participation in PESQOL; 39 (17%) declined; and 14 (6%) consented, but later withdrew. Of the 173 enrolled at baseline, 163 had reached the 6-month postenrollment phase, and 118 of those participants completed follow-up questionnaires.

### Standard protocol approvals, registrations, and patient consents

The study received approval from the ethics boards of all participating hospitals and assent or consent was obtained from each participant.

### Measures

*QOL measures*

QOL was assessed using the original version of the Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-76)[1,2] and the KIDSCREEN-27.[10] The QOLCE-76 is a 76-item parent-rated epilepsy-specific instrument composed of five main domains: physical activity (physical restrictions and energy/fatigue), cognition (attention/concentration, memory, language, and other cognition), well-being (depression, anxiety, control/helplessness, and self-esteem), social activity (social interactions, social activities, and stigma), and behavior. The QOLCE-76 also includes an overall quality of life item that asked, "In the past 4 weeks, what has your child's quality of life been?" with the item rated on a five-point Likert scale from *excellent* to *poor*. The composite QOL score is the unweighted average of 16 QOLCE-76 subscales, ranging from 0 to 100, with the exclusion of the overall QOL item. Higher scores indicate better QOL. The QOLCE-76 has good validity and reliability.[1,2] The KIDSCREEN-27 is a dual child- and parent-rated generic health-related quality of life (HRQL) instrument that measures five dimensions: physical well-being (five items), psychological well-being (seven items), parental relations and autonomy (seven items), social support and peers (four items), and school environment (four items). Because the QOLCE-76 is a parent-report questionnaire, we used only the results from the parent form of the KIDSCREEN-27. Rasch scores are computed for each dimension and are transformed into values with a mean of 50 and a standard deviation of 10. Higher scores indicate better

QOL. The composite score is the unweighted average of the five KIDSCREEN-27 subscales. The KIDSCREEN-27 has good internal consistency reliability ($\alpha$ = 0.79–0.84) and test-retest reliability (r = 0.61–0.74), and good convergent and discriminant validity.[10]

*Potential correlates of QOL*

Age at seizure onset, duration of epilepsy, number of AEDs, seizure frequency, and surgery status were collected from medical records. Seizure frequency was operationalized as a binary variable with levels of low seizure frequency (monthly or less) versus high seizure frequency (daily, weekly). IQ of all patients was assessed using the Wechsler Abbreviated Scale of Intelligence-II (ages 6–18 years)[11] or the Wechsler Preschool and Primary Scale of Intelligence-IV (ages 4–5 years).[12] Household income and caregiver employment status were collected through a parent questionnaire.[13]

Caregiver's anxiety was assessed with the Generalized Anxiety Disorder-7,[14] a 7-item self-report instrument (score range: 0–21, $\alpha$ = 0.92). Caregiver depression was measured with the Quick Inventory of Depressive Symptomatology,[15] a 16-item self-report measure (score range: 0–27, $\alpha$ = 0.82). For both scales, higher scores indicate greater impairment.

In terms of the family environment, family adaptation was measured with the Family Adaptability, Partnership, Growth, Affection, and Resolve (Family APGAR),[16,17] a 5-item self-report instrument that assessed satisfaction with family relationships (score range: 0–20, $\alpha$ = 0.80). Resources available to aid families' adaptation to stress events were quantified using two subscales (family mastery and health, extended family social support) from the Family Inventory of Resources for Management (FIRM)[18] (score range: 0–72, $\alpha$ = 0.91). Family demands were measured using the Family Inventory of Life Events and Changes (FILE),[19] a 71-item self-report scale that quantified the accumulation of simultaneous normal and nonnormal life events and changes in life events experienced by a family during the previous year (score range: 0–71, $\alpha$ = 0.83). All instruments have been shown to have acceptable reliability and validity.[15,17–20]

**Statistical analyses**

All analyses were conducted using R (version 3.1.0 for Windows). Descriptive statistics used to describe the sample included mean and standard deviation for continuous measures, and frequency and percentages for categorical variables. Before proceeding with data analysis, all variables were screened for missing data. Two variables (number of AEDs and family demands at baseline) had <1% missing data, whereas number of AEDs at follow-up and IQ had 11% and 9% missing data, respectively. Results of Little's MCAR test suggested that data were missing completely at random, $\chi^2$ (168) = 191.56, p = 0.103.

Construct validity was examined by measuring the correlation of the G-QOLCE with QOLCE-76 composite score (excluding the QOL item) and five main domains, as well as KIDSCREEN-27 composite score and five subscales, at baseline and 6-month follow-up. Spearman rank-correlation coefficients were analyzed, with correlations of 0.10–0.30 regarded as weak; 0.30–0.50 as moderate; and >0.50 as strong.[21]

Test-retest reliability of G-QOLCE was examined in those with "stable" QOLCE-76 composite scores (excluding the QOL item) and main domains, as well as KIDSCREEN-27 composite scores and subscales, from baseline to 6 months. We used a standard error of measurement (SEM)-based criterion to identify children who experienced clinically meaningful changes in QOL from baseline to 6 months.[13] When employing psychometrically robust measures of QOL, scores of at least one SEM are considered to represent clinically important intraindividual changes in QOL.[13,22] Consequently, patients were classified as "stable" on the QOL measures if scores differed by less than one SEM from baseline to 6 months and "changed" if there was at least a one-SEM difference during this time period. Intraclass correlation coefficient (ICC) with 95% confidence interval (CI) was calculated for each "stable" subgroup from baseline to 6 months. For reliability of measurements over time, we employed the conventional interpretation of the ICC such that values of 0.40–0.75 were considered fair to good and values over 0.75 were considered excellent.[23] Further, given the ordinal nature of the G-QOLCE scale, Wilcoxon signed rank tests for paired comparisons were employed to assess whether there were significant differences in G-QOLCE scores from baseline to 6 months in the stable subgroups.

To assess clinically relevant change, responsiveness was examined through the distribution-based and anchor-based methods. For the distribution-based approach, we calculated G-QOLCE difference scores from baseline to 6-month follow-up and examined (1) the standardized response mean (SRM), calculated as the mean change in score divided by the standard deviation of change;[24] and (2) the probability of change statistic, calculated on the basis of the cumulative normal distribution.[25] A probability of change statistic greater than 0.5 (range: 0.5–1.0) suggests that a measure can detect change.[25] For anchor-based methods, we calculated difference scores from baseline to 6-month follow-up in composite scores of the QOLCE-76 (excluding the overall QOL item) and the KIDSCREEN-27. As described above, patients were classified as "stable" on the QOL measures if scores differed by less than one SEM from baseline to 6 months and "changed" if there was at least a one-SEM difference during this time period. We evaluated Guyatt's responsiveness statistic for "changed" subgroups, calculated as the mean change in score divided by the standard deviation of change in stable subjects and interpreted according to the following Cohen's effect size conventions: small (0.2), moderate (0.5), or large (0.8).[26]

Ordered logistic regression was employed to examine the association between the G-QOLCE scores and identified correlates of QOL in children with epilepsy[7,8] at both time points. Potential correlates included seizure frequency, IQ, number of AEDs, duration of epilepsy, caregiver anxiety, caregiver depression, family functioning, family resources, family demands (measured at baseline only), and household income. There was evidence of multicollinearity as assessed by variance inflation factor values (VIF >2) for caregiver depression, caregiver anxiety, and family resources at baseline and 6 months. We first removed family resources from the analyses and reevaluated VIF values, which remained high for caregiver depression and caregiver anxiety. Consequently, given that caregiver anxiety has been identified as an important risk factor of child HRQL in a recent meta-analysis,[8] we removed caregiver depression from the analyses. With a sample of 118, we were powered to detect medium-sized effects at 0.8 statistical power (analyzed with G*Power).

## Results

The characteristics of the 118 participants are presented in Table 1. At baseline, children had a mean age of 11.51 ± 3.94 years and 74 (58%) were male. The mean age at seizure onset was 6.49 ± 4.10 years, and the average duration of epilepsy was 4.99 ± 3.98 years. Approximately 53% of the sample experienced seizures daily or weekly. Fig. 1 illustrates the distribution of G-QOLCE scores at baseline and 6-month follow-up.

### Construct validity

The associations between G-QOLCE scores with QOLCE-76 composite scores (excluding the QOL item), QOLCE-76 main domains, KIDSCREEN-27 composite scores, and KIDSCREEN-27 subscales at baseline and 6-month follow-up are summarized in Table 2. All correlations were statistically significant at $p < 0.01$. The majority of QOLCE-76 domains and KIDSCREEN-27 subscales were moderately correlated with G-QOLCE scores. The G-QOLCE scores were strongly correlated with composite scores of the QOLCE-76 and main domains of *physical activity* (6 months) and *social activity* (6 months), and with the KIDSCREEN-27 composite scores and the *physical well-being* and *psychological well-being* subscales. The strength of the correlations increased over time, with the exception of QOLCE-76 *well-being* domain.

### Test-retest reliability

Table 3 presents a summary of the test-retest reliability analyses for G-QOLCE scores from baseline to 6 months among "stable" patients. Overall, the majority of G-QOLCE scores did not change over time (31.1–62.1%) for those identified as clinically stable on the basis of QOLCE-76 composite scores (excluding the QOL item) and main domains, as well as KIDSCREEN-27 composite scores and subscales. In these stable subgroups, G-QOLCE scores varied by ±3 points at most from baseline to 6 months; however, the large majority of patients showed no change or close to no change.

Intraclass correlation coefficient values ranged between 0.49 and 0.72, highest for the subgroup with stable QOLCE-76 composite score, and lowest for the subgroup with stable *parental relationships & autonomy* subscale of the KIDSCREEN-27. Results of Wilcoxon signed rank tests for paired comparisons showed no significant difference ($p > 0.05$) only for subgroups classified as stable based on QOLCE-76 composite scores, QOLCE-76 *physical activity* and *well-being* domains, and the *school environment* subscale of the KIDSCREEN-27 only.

### Responsiveness

For distribution-based methods, the SRM for the comparison of G-QOLCE scores from baseline to 6-month follow-up was −0.38 (95% CI, −0.55 to −0.19), and the related probability of change was 0.65 (95% CI, 0.56, 0.71), suggesting that the G-QOLCE is able to detect changes in patient QOL. For anchor-based-methods, G-QOLCE scores from baseline to 6-month follow-up demonstrated a moderate magnitude of change for patients who "changed" based on the composite scores of the QOLCE-76 excluding the QOL item (Guyatt's responsiveness statistic = 0.62, n = 89) and the KIDSCREEN-27 (Guyatt's responsiveness statistic = 0.78, n = 40).

### Correlates of QOL

Results of the ordered logistic regression models fit for the outcome of G-QOLCE scores at baseline and 6-month follow-up are presented in Table 4. Household income explained the most variation in G-QOLCE scores at baseline, followed by caregiver anxiety and family functioning. At 6-month follow-up, caregiver anxiety explained the most variation in G-QOLCE scores, followed by seizure frequency and family functioning.

## Discussion

It has been argued that, rather than proliferating new epilepsy-specific QOL measures, the QOL measurement initiative in epilepsy is best served by fine-tuning and building the evidence base around existing instruments.[6] Consequently, we selected the general QOL item from the QOLCE-76 for validation as a global measure because the QOLCE has been identified as the current gold standard for assessing QOL in children with epilepsy.[27] The current study provides evidence on construct validity, test-retest reliability, and responsiveness of the G-QOLCE, in a multicenter sample of children with drug-resistant epilepsy.

Construct validity of the G-QOLCE was supported by moderate to strong correlations with composite and subscale

**Table 1. Characteristics of children with epilepsy and caregivers**

| | Baseline (n = 118) | 6 months (n = 118) |
|---|---|---|
| *Child characteristics* | | |
| Age, years (SD) | 11.51 (3.94) | 12.07 (4.00) |
| Sex, n (%) | | |
| Male | 74 (57.6) | |
| Female | 45 (43.4) | |
| Age (years) at seizure onset (SD) | 6.49 (4.10) | |
| Duration (years) of epilepsy (SD) | 4.99 (3.98) | 5.61 (4.06) |
| Seizure frequency, n (%) | | |
| High (daily or weekly) | 63 (53.4) | 36 (30.5) |
| Low (monthly or less) | 55 (46.6) | 82 (72.6) |
| Number of antiseizure medications (SD) | 1.80 (0.80) | 1.87 (0.89) |
| Surgery status, n (%) | | |
| Yes | – | 36 (32.1) |
| No | – | 76 (68.0) |
| Quality of life | | |
| QOLCE-76 (SD) | 60.47 (15.82) | 64.07 (16.38) |
| Global QOL item, n (%) | | |
| Excellent | 16 (13.56) | 27 (22.88) |
| Very good | 30 (25.42) | 40 (33.90) |
| Good | 49 (41.53) | 39 (33.05) |
| Fair | 20 (16.95) | 10 (847) |
| Poor | 3 (2.54) | 2 (1.69) |
| KIDSCREEN-27 (parent report, raw scores) | | |
| Physical well-being | 42.25 (9.48) | 44.53 (10.81) |
| Psychological well-being | 43.29 (9.07) | 45.47 (11.70) |
| Parent relationships & autonomy | 50.26 (9.80) | 52.32 (9.29) |
| Social support & peers | 44.21 (13.41) | 46.47 (11.80) |
| School environment | 45.79 (10.45) | 47.23 (9.39) |
| IQ (SD) | 86.4 (18.26) | – |
| *Family characteristics* | | |
| Caregiver employment status n (%) | | |
| Employed | 87 (73.7) | 94 (79.7) |
| Not employed | 31 (26.3) | 24 (20.3) |
| Caregiver anxiety, GAD | 5.40 (5.38) | 4.18 (4.49) |
| Caregiver depression, QIDS | 5.92 (3.96) | 4.89 (4.05) |
| Family functioning, APGAR | 7.24 (2.19) | 7.48 (2.26) |
| Family resources, FIRM | 49.58 (11.35) | 50.90 (11.62) |
| Family demands, FILE | 9.14 (6.29) | – |
| Income, n (%) | | |
| Prefer not to say | 8 (6.78) | 11 (9.32) |
| <$60,000 | 20 (16.95) | 21 (17.80) |
| ≥$60,000 | 90 (76.27) | 86 (72.88) |

APGAR, Family Adaptability, Partnership, Growth, Affection, and Resolve; FILE, Family Inventory of Life Events and Changes; FIRM, Family Inventory of Resources for Management; GAD, Generalized Anxiety Disorder scale; QIDS, quick inventory of depressive symptomatology; QOL, quality of life; QOLCE, Quality of life in Childhood Epilepsy Questionnaire; SD, standard deviation.

scores from two QOL questionnaires, the QOLCE-76 and the KIDSCREEN-27, with the exception of the *social support & peers* subscale of the KIDSCREEN-27 at baseline. Further, results of the distribution-based and anchor-based approaches support the responsiveness of the G-QOLCE, suggesting that the single-item measure is able to detect clinically important changes in patient QOL.

To examine test-retest reliability, we employed a broader definition of stability that used a standard error of measurement (SEM)-based criterion to identify children who experienced clinically meaningful changes in QOL from baseline to 6 months. This method is in line with previous work suggesting that a "zero-change" approach to assessing stability in single-item scales may be overrestrictive and less meaningful in clinical settings.[28] ICC values for subgroups of clinically stable patients were considered fair to good. However, results of paired comparisons suggested that there were significant differences in G-QOLCE scores from baseline to 6 months in the stable subgroups for most subscales and composite scores of the QOL measures. One plausible explanation for the reduced test-retest reliability is the 6-month interval between test administrations, which is longer than most studies examining test-retest reliability for QOL instruments. Longer time intervals typically result in lower

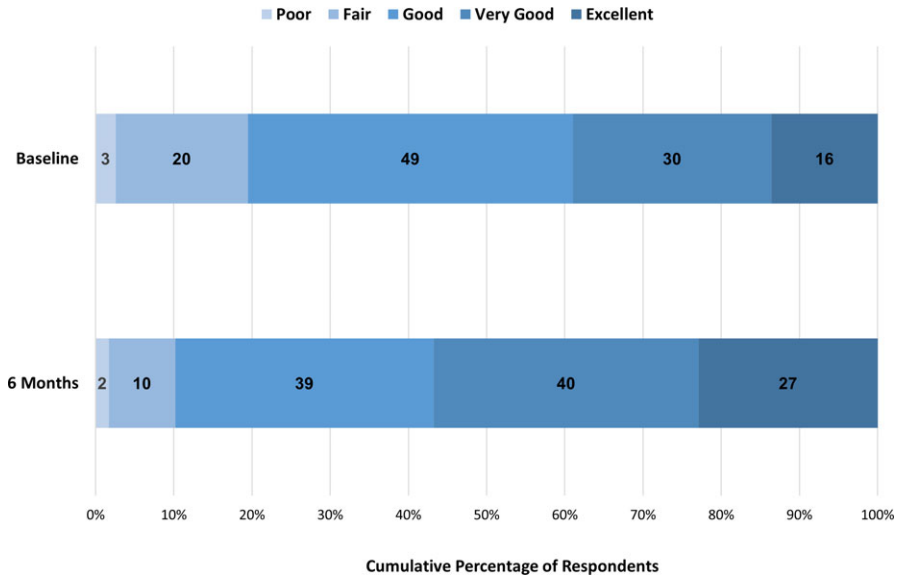


**Figure 1.**
Stacked bar graphs depicting the distribution of G-QOLCE scores at baseline and 6 months; "In the past 4 weeks, what has your child's quality of life been?" The data labels indicate participant counts (n = 118).
*Epilepsia Open* © ILAE

**Table 2. Spearman rank correlations of G-QOLCE scores with composite and subscale scores of the QOLCE-76 and KIDSCREEN-27 at baseline and 6-month follow-up**

| | Baseline | | 6 months | |
|---|---|---|---|---|
| | Spearman Rho | p | Spearman Rho | p |
| QOLCE-76 | | | | |
| Physical activity | 0.482 | <0.001 | 0.537 | <0.001 |
| Cognition | 0.322 | <0.001 | 0.391 | <0.001 |
| Well-being | 0.376 | <0.001 | 0.371 | <0.001 |
| Social activity | 0.486 | <0.001 | 0.595 | <0.001 |
| Behavior | 0.399 | <0.001 | 0.437 | <0.001 |
| Composite score[a] | 0.539 | <0.001 | 0.611 | <0.001 |
| KIDSCREEN-27 (parent report) | | | | |
| Physical well-being | 0.500 | <0.001 | 0.545 | <0.001 |
| Psychological well-being | 0.515 | <0.001 | 0.566 | <0.001 |
| Parent relationships & autonomy | 0.324 | <0.001 | 0.371 | <0.001 |
| Social support & peers | 0.271 | 0.003 | 0.460 | <0.001 |
| School environment | 0.362 | <0.001 | 0.470 | <0.001 |
| Composite score | 0.517 | <0.001 | 0.625 | <0.001 |

QOLCE, Quality of life in Childhood Epilepsy Questionnaire.
[a]Composite QOLCE-76 score minus the general quality of life item.

reliability coefficients owing to the potential for clinical change in patients.

As a secondary aim, we examined potential correlates of the G-QOLCE ratings. Caregiver anxiety and caregiver satisfaction with family relationships contributed most strongly to child QOL over time. This finding is consistent with previous research highlighting the dominant effects of psychosocial factors, such as parental psychopathology and the family environment more broadly, on child QOL at baseline[7] and longitudinally,[29,30] relative to clinical factors. One exception is AED side effects, a seizure-related variable that was not captured in the current study but that has been identified as a consistent predictor of QOL in children with epilepsy.[8,30]

Although this is the first study to examine the measurement properties of a single-item measure of QOL in pediatric epilepsy, global assessments of QOL have been utilized and validated across a spectrum of neurological and nonneurological disorders.[31,32] As compared to multi-item scales, a single-item measure provides a broad summary rating of patient QOL; is

**Table 3. Test-retest reliability (ICC and Wilcoxon signed rank test) for G-QOLCE scores from baseline to 6 months among "stable" patients**

| | Determining stability | | | | | Test-retest reliability | |
|---|---|---|---|---|---|---|---|
| External indicator | SD | Internal consistency[a] | SEM | Stable (n) | No (0) change in QOL single-item scores, n (%) | ICC (95% CI) | Wilcoxon signed rank test (V) |
| QOLCE-76 | | | | | | | |
| Physical activity | 15.60 | 0.83 | 6.43 | 47 | 25 (53.2) | 0.70 (0.51, 0.82) | 74 (p = 0.063) |
| Cognition | 22.64 | 0.97 | 3.92 | 35 | 21 (60.0) | 0.67 (0.44, 0.82) | 20 (p = 0.037) |
| Well-being | 15.71 | 0.93 | 4.16 | 38 | 19 (50.0) | 0.62 (0.38, 0.79) | 75 (p = 0.404) |
| Social activity | 26.34 | 0.93 | 6.97 | 44 | 20 (45.5) | 0.64 (0.43, 0.79) | 44 (p = 0.001) |
| Behavior | 15.71 | 0.86 | 5.89 | 66 | 31 (47.0) | 0.63 (0.46, 0.76) | 179 (p = 0.018) |
| Composite score[b] | 16.11 | 0.97 | 2.79 | 29 | 18 (62.1) | 0.72 (0.50, 0.86) | 30 (p = 0.850) |
| KIDSCREEN-27 (parent report) | | | | | | | |
| Physical well-being | 3.66 | 0.84 | 1.46 | 45 | 14 (31.1) | 0.68 (0.48,0.81) | 27 (p = 0.002) |
| Psychological well-being | 4.39 | 0.88 | 1.52 | 43 | 24 (55.8) | 0.64 (0.42,0.79) | 43 (p = 0.026) |
| Parent relationships & autonomy | 4.12 | 0.80 | 1.84 | 49 | 25 (51.0) | 0.49 (0.24,0.67) | 82 (p = 0.037) |
| Social support & peers | 3.83 | 0.93 | 1.01 | 47 | 26 (55.3) | 0.64 (0.44,0.79) | 55 (p = 0.026) |
| School environment | 3.17 | 0.84 | 1.27 | 57 | 32 (56.1) | 0.52 (0.31,0.69) | 96 (p = 0.060) |
| Composite score | 2.90 | 0.93 | 0.78 | 78 | 43 (55.1) | 0.62 (0.47, 0.74) | 194 (p = 0.034) |

CI, confidence interval; ICC, intraclass correlation coefficient; QOL, quality of life; QOLCE, Quality of life in Childhood Epilepsy Questionnaire; SD, standard deviation; SEM, standard error of measurement.
[a]Internal consistency measured using Cronbach α.
[b]Composite QOLCE-76 score minus the global quality of life item.

**Table 4. Ordered logistic regression analyses for the cross-sectional association between G-QOLCE scores and identified correlates of QOL in children with epilepsy at baseline and 6 months**

| | Baseline | | | 6 months | | |
|---|---|---|---|---|---|---|
| | B | SE | p | B | SE | p |
| Intercept | | | | | | |
| Poor \| Fair | −2.09 | 1.67 | 0.210 | −9.99 | 0.02 | 0.000* |
| Fair \| Good | 0.51 | 1.58 | 0.743 | −0.56 | 1.56 | 0.762 |
| Good \| Very good | 2.79 | 1.61 | 0.083 | 2.16 | 1.84 | 0.241 |
| Very good \| Excellent | 4.66 | 1.66 | 0.005* | 4.11 | 1.89 | 0.029* |
| Child factors | | | | | | |
| Seizure frequency | −0.69 | 0.40 | 0.086 | −1.28 | 0.49 | 0.009* |
| IQ | 0.00 | 0.01 | 0.700 | 0.01 | 0.01 | 0.592 |
| Number of antiepileptic drugs | −0.38 | 0.25 | 0.131 | −0.35 | 0.35 | 0.167 |
| Duration of epilepsy | 0.06 | 0.06 | 0.247 | 0.06 | 0.06 | 0.313 |
| Family factors | | | | | | |
| Caregiver employment status | 0.39 | 0.48 | 0.423 | −0.07 | 0.57 | 0.902 |
| Caregiver anxiety, GAD | −0.11 | 0.05 | 0.021* | −0.20 | 0.07 | 0.005* |
| Family functioning, APGAR | 0.22 | 0.10 | 0.022* | 0.26 | 0.10 | 0.012* |
| Family demands, FILE | 0.02 | 0.04 | 0.698 | – | – | – |
| Income | 0.21 | 0.07 | 0.006* | 0.15 | 0.08 | 0.070 |
| −2 log likelihood | | −116.51 | | | −91.58 | |
| AIC | | 259.02 | | | 205.16 | |
| Residual deviance | | 230.02 | | | 183.17 | |

AIC, Akaike Information Criterion; APGAR, Family Adaptability, Partnership, Growth, Affection, and Resolve; GAD, Generalized Anxiety Disorder scale; B, parameter estimate; FILE, Family Inventory of Life Events and Changes; SE, standard error.
*$p < 0.05$.

useful in the assessment of health transitions (e.g., "better, same, or worse"); and can be feasibly implemented in busy clinical settings.[33] More broadly, information garnered from patient-reported QOL assessment in clinical practice has been found to enhance patient-physician communication about QOL-related problems, improve patient satisfaction with care, and affect patient management.[34–36] Recognizing the reported practical barriers to implementation such as lack of time and impracticality of instruments,[35] the main potential advantage of a single-item QOL measure is its brevity and ease of use in clinical encounters.[37] If a parent reports a change in QOL relative to that of the previous visit, the clinician can then probe

with additional questions for the reason for the change and manage accordingly. However, single-item assessments are not without disadvantages. Relative to multi-item measures, global assessments are more prone to random error and generate inferior discriminatory power.[38] Taken together, a psychometrically sound, single-item measure of QOL for pediatric epilepsy can provide meaningful information to neurologists and other health practitioners aiming to monitor treatment progress of patients, while keeping respondent and administrative burden to a minimum.

Several limitations of the current study are noteworthy. The G-QOLCE is a parent-report measure and, as such, issues of informant discordance (parent vs. child) are relevant. Although measures allowed for comparisons of the G-QOLCE with other highly utilized measures of QOL in children with epilepsy, thus enhancing construct validity, only parent-report measures were examined. A recent study[29] has documented general agreement in the trajectories of child- versus parent-reported QOL in children with epilepsy, supporting previous evidence that parents are valid proxy informants.[39] However, slight differences in trajectory profiles suggest that multi-informant approaches are important to provide a broader view of child QOL over time. Further, given that validity differs according to population and context, results of the current investigation apply to children with drug-resistant epilepsy. Future research is needed to validate the G-QOLCE in different populations of children with epilepsy. Whereas the larger PESQOL study is designed to evaluate the effectiveness of epilepsy surgery relative to medical therapy (AEDs) on improving QOL over 2 years, the current study utilized data at baseline and 6-month follow-up only. Consequently, given that surgical outcome classification systems (i.e., Engel and International League Against Epilepsy [ILAE][40]) are usually applied to patients with at least 1-year follow-up, we did not quantify change based on treatment group when examining the clinical responsiveness of the G-QOLCE.

## Conclusion

The current study is the first, to our knowledge, to examine the psychometric properties of a single-item QOL measure in children with epilepsy. Results offer promising preliminary evidence regarding the validity, reliability, and responsiveness of the G-QOLCE in a sample of children with drug-resistant epilepsy, suggesting that it is a potentially useful tool that can be used by neurologists to evaluate clinical status and influence treatment outcomes in pediatric epilepsy.

## Acknowledgments

PEPSQOL was funded by a grant from the Canadian Institutes for Health Research (MOP-133708) to E.W. and M.L.S. L.C. is supported by a doctoral fellowship from the Social Sciences and Humanities Research Council.

## Disclosure

None of the authors has any conflicts of interest to disclose. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

## References

1. Sabaz M, Cairns DR, Lawson JA, et al. Validation of a new quality of life measure for children with epilepsy. *Epilepsia* 2000;41:765–774.
2. Sabaz M, Lawson JA, Cairns DR, et al. Validation of the Quality of Life in Childhood Epilepsy Questionnaire in American epilepsy patients. *Epilepsy Behav* 2003;4:680–691.
3. Goodwin SW, Lambrinos AI, Ferro MA, et al. Development and assessment of a shortened Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-55). *Epilepsia* 2015;56:864–872.
4. Conway L, Widjaja E, Smith ML, et al. Validating the shortened Quality of Life in Childhood Epilepsy Questionnaire (QOLCE-55) in a sample of children with drug-resistant epilepsy. *Epilepsia* 2017;58:646–656.
5. Ronen GM, Streiner DL, Rosenbaum P. Health-related quality of life in childhood epilepsy: moving beyond "seizure control with minimal adverse effects." *Health Qual Life Outcomes* 2003;1:36.
6. Jacoby A, Baker GA, Crossley J, et al. Tools for assessing quality of life in epilepsy patients. *Expert Rev Neurother* 2013;13:1355–1369.
7. Conway L, Smith ML, Ferro MA, et al. Correlates of health-related quality of life in children with drug resistant epilepsy. *Epilepsia* 2016;57:1256–1264.
8. Ferro MA. Risk factors for health-related quality of life in children with epilepsy: a meta-analysis. *Epilepsia* 2014;55:1722–1731.
9. Wagner AK, Ehrenberg BL, Tran TA, et al. Patient-based health status measurement in clinical practice: a study of its impact on epilepsy patients' care. *Qual Life Res* 1997;6:329–341.
10. Ravens-Sieberer U, Auquier P, Erhart M, et al. The KIDSCREEN-27 quality of life measure for children and adolescents: psychometric results from a cross-cultural survey in 13 European countries. *Qual Life Res* 2007;16:1347–1356.
11. Wechsler D. *Wechsler Abbreviated Scale of Intelligence (WASI) manual*. San Antonio, TX: The Psychological Corporation; 2011.
12. Wechsler D. *Technical and interpretive manual for the Wechsler Preschool and Primary Scale of Intelligence*. San Antonio, TX: The Psychological Corporation; 2012.
13. Speechley KN, Ferro MA, Camfield CS, et al. Quality of life in children with new-onset epilepsy: a 2-year prospective cohort study. *Neurology* 2012;79:1548–1555.
14. Spitzer RL, Kroenke K, Williams JB, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–1097.
15. Bernstein IH, Rush AJ, Trivedi MH, et al. Psychometric properties of the Quick Inventory of Depressive Symptomatology in adolescents. *Int J Methods Psychiatr Res* 2010;19:185–194.
16. Smilkstein G. The family APGAR: a proposal for a family function test and its use by physicians. *J Fam Pract* 1978;6:1231–1239.
17. Smilkstein G, Ashworth C, Montano D. Validity and reliability of the family APGAR as a test of family function. *J Fam Pract* 1982;15:303–311.
18. McCubbin HI, Thompson AI, McCubbin MA. *FIRM: Family Inventory of Resources for Management. Family assessment: resiliency, coping and adaptation. Inventories for research and practice*. Madison, WI: University of Wisconsin Publishers; 1996a.
19. McCubbin HI, Thompson AI, McCubbin MA. *FILE: Family Inventory of Life Events and Changes. Family assessment: resiliency, coping and adaptation. Inventories for research and practice*. Madison, WI: University of Wisconsin Publishers; 1996b.
20. Löwe B, Decker O, Müller S, et al. Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. *Med Care* 2008;46:266–274.
21. Cohen J. *Statistical power analysis for the behavioral sciences*. New York, NY: Academic Press; 1969.
22. Wyrwich KW, Tierney WM, Wolinsky FD. Further evidence supporting an SEM-based criterion for identifying meaningful intra-individual

changes in health-related quality of life. *J Clin Epidemiol* 1999;52:861–873.
23. Fleiss JL. Analysis of data from multiclinic trials. *Control Clin Trials* 1986;7:267–275.
24. Husted JA, Cook RJ, Farewell VT, et al. Methods for assessing responsiveness: a critical review and recommendations. *J Clin Epidemiol* 2000;53:459–468.
25. Zou GY. Quantifying responsiveness of quality of life measures without an external criterion. *Qual Life Res* 2005;14:1545–1552.
26. Cohen J. *The significance of a product moment r statistical power analysis for the behavioural sciences*. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
27. Stevanovic D. Comments on health-related quality of life measures for children and adolescents with epilepsy. *Value Health* 2008;11:788.
28. Chan CJ, Zou G, Wiebe S, et al. Global Assessment of the Severity of Epilepsy (GASE) Scale in children: validity, reliability, responsiveness. *Epilepsia* 2015;56:1950–1956.
29. Ferro MA, Avery L, Fayed N, et al. Child- and parent-reported quality of life trajectories in children with epilepsy: a prospective cohort study. *Epilepsia* 2017;21:e5.
30. Wu YP, Follansbee-Junger K, Rausch J, et al. Parent and family stress factors predict health-related quality in pediatric patients with new-onset epilepsy. *Epilepsia* 2014;55:866–877.
31. Locke DE, Decker PA, Sloan JA, et al. Validation of single-item linear analog scale assessment of quality of life in neuro-oncology patients. *J Pain Symptom Manage* 2007;34:628–638.
32. Siebens HC, Tsukerman D, Adkins RH, et al. Correlates of a single-item quality-of-life measure in people aging with disabilities. *Am J Phys Med Rehabil* 2015;94:1065.
33. Bowling A. *Just one question: if one question works, why ask several? London*. UK: BMJ Publishing Group Ltd; 2005.
34. Uzark K, King E, Spicer R, et al. The clinical utility of health-related quality of life assessment in pediatric cardiology outpatient practice. *Congenit Heart Dis* 2013;8:211–218.
35. Gutteling JJ, Busschbach JJ, de Man RA, et al. Logistic feasibility of health related quality of life measurement in clinical practice: results of a prospective study in a large population of chronic liver patients. *Health Qual Life Outcomes* 2008;6:97.
36. Varni JW, Burwinkle TM, Lane MM. Health-related quality of life measurement in pediatric clinical practice: an appraisal and precept for future research and application. *Health Qual Life Outcomes* 2005;3:34.
37. Yohannes AM, Dodd M, Morris J, et al. Reliability and validity of a single item measure of quality of life scale for adult patients with cystic fibrosis. *Health Qual Life Outcomes* 2011;9:105.
38. Fayers PM, Hand DJ. Causal variables, indicator variables and measurement scales: an example from quality of life. *J R Stat Soc Series A Stat Soc* 2002;165:233–253.
39. Ferro MA, Avison WR, Campbell MK, et al. The impact of maternal depressive symptoms on health-related quality of life in children with epilepsy: a prospective study of family environment as mediators and moderators. *Epilepsia* 2011;52:316–325.
40. Durnford AJ, Rodgers W, Kirkham FJ, et al. Very good inter-rater reliability of Engel and ILAE epilepsy surgery outcome classifications in a series of 76 patients. *Seizure* 2011;20:809–812.