Title

PedsQL 3.2 Diabetes Module for Children, Adolescents, and Young Adults: Reliability and Validity in Type 1 Diabetes

Journal

Diabetes Care, 41(10)

ISSN

1066-9442

Authors

Varni, James W
Delamater, Alan M
Hood, Korey K
et al.

Publication Date

2018-10-01

DOI

10.2337/dc17-2707

Peer reviewed

PedsQL 3.2 Diabetes Module for Children, Adolescents, and Young Adults: Reliability and Validity in Type 1 Diabetes

Diabetes Care 2018;41:2064–2071 | https://doi.org/10.2337/dc17-2707

*James W. Varni,[1] Alan M. Delamater,[2] Korey K. Hood,[3] Jennifer K. Raymond,[4] Nancy T. Chang,[4] Kimberly A. Driscoll,[5] Jenise C. Wong,[6] Joyce P. Yi-Frazier,[7] Ellen K. Grishman,[8] Melissa A. Faith,[8] Sarah D. Corathers,[9] Jessica C. Kichler,[10] Jennifer L. Miller,[11] Elena M. Doskey,[12] Robert W. Heffer,[13] and Don P. Wilson,[14] on behalf of the Pediatric Quality of Life Inventory 3.2 Diabetes Module Testing Study Consortium**

OBJECTIVE

The objective of the study was to report on the measurement properties of the revised and updated Pediatric Quality of Life Inventory (PedsQL) 3.2 Diabetes Module for children, adolescents, and young adults with type 1 diabetes.

RESEARCH DESIGN AND METHODS

The 33-item PedsQL 3.2 Diabetes Module and PedsQL Generic Core Scales were completed in a 10-site national field test study by 656 families of patients ages 2–25 years with type 1 diabetes.

RESULTS

The 15-item Diabetes Symptoms Summary Score and 18-item Diabetes Management Summary Score were derived from the factor analysis of the items. The Diabetes Symptoms and Diabetes Management Summary Scores evidenced excellent reliability (patient self-report α = 0.88–0.90; parent proxy report α = 0.89–0.90). The Diabetes Symptoms and Diabetes Management Summary Scores demonstrated construct validity through medium to large effect size correlations with the Generic Core Scales Total Scale Score (r = 0.43–0.67, $P < 0.001$). HbA_{1c} was significantly correlated with the Diabetes Symptoms and Diabetes Management Summary Scores ($r = -0.21$ to -0.29, $P < 0.001$). Minimal clinically important difference scores ranged from 5.05 to 5.55.

CONCLUSIONS

The PedsQL 3.2 Diabetes Module Diabetes Symptoms and Diabetes Management Summary Scores demonstrated excellent measurement properties and may be useful as standardized patient-reported outcomes of diabetes symptoms and diabetes management in clinical research, clinical trials, and practice in children, adolescents, and young adults with type 1 diabetes.

The international incidence and prevalence of type 1 diabetes have increased significantly over the past several decades in children, adolescents, and young adults (1–3). Measuring the patient's perspective of the impact of diabetes on daily living has become even more important as the emphasis on personalized medicine and tailored interventions requires shared decision making between the patient and health care providers regarding risk assessment and evidence-based treatment choices (4).

The Pediatric Quality of Life Inventory (PedsQL) 3.0 Diabetes Module (www.pedsql.org) is one of the most widely used internationally validated patient-reported

[1]Department of Pediatrics, College of Medicine, and Department of Landscape Architecture and Urban Planning, College of Architecture, Texas A&M University, College Station, TX
[2]Mailman Center for Child Development, Department of Pediatrics, University of Miami Miller School of Medicine, Miami, FL
[3]Division of Pediatric Endocrinology and Diabetes, Department of Pediatrics, Stanford University School of Medicine, Stanford, CA
[4]Division of Endocrinology, Diabetes and Metabolism, Children's Hospital Los Angeles, Los Angeles, CA
[5]Department of Pediatrics, Barbara Davis Center for Diabetes, University of Colorado Denver, Denver, CO
[6]The Madison Clinic for Pediatric Diabetes and Division of Endocrinology, Department of Pediatrics, University of California, San Francisco, San Francisco, CA
[7]Seattle Children's Research Institute, Seattle, WA
[8]Division of Pediatric Endocrinology, Department of Pediatrics, University of Texas Southwestern Medical Center, Dallas, TX
[9]Division of Endocrinology, Department of Pediatrics, Cincinnati Children's Hospital Medical Center, University of Cincinnati College of Medicine, Cincinnati, OH
[10]Division of Behavioral Medicine and Clinical Psychology, Department of Pediatrics, Cincinnati Children's Hospital Medical Center, University of Cincinnati College of Medicine, Cincinnati, OH
[11]Division of Pediatric Endocrinology, Department of Pediatrics, Ann and Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, IL
[12]Department of Educational Psychology, Texas A&M University, College Station, TX
[13]Department of Psychological & Brain Sciences, Texas A&M University, College Station, TX
[14]Cook Children's Medical Center, Fort Worth, TX

Corresponding author: James W. Varni, jvarni@tamu.edu.

Received 28 December 2017 and accepted 6 July 2018.

outcome (PRO) measures to assess diabetes-specific health-related quality of life (HRQOL) of children, adolescents, and young adults from the perspective of both pediatric patients and their parents (5–8). Prior studies using the PedsQL 3.0 Diabetes Module have demonstrated the measure's reliability and validity in children, adolescents, and young adults with type 1 diabetes (6,8). Nonetheless, the PedsQL 3.0 Diabetes Module was developed almost 20 years ago, and evolving differences in treatment regimens and the use of the measure in young adult patients warranted additional qualitative methods research on the content validity of the instrument for current use.

To establish contemporary content validity, we used qualitative methods as recommended by the U.S. Food and Drug Administration (9) and the PRO measurement literature (10,11) to develop new items and revise and delete existing items as needed, resulting in the PedsQL 3.2 Diabetes Module (12). However, we have not previously reported on the measurement properties of the new 33-item PedsQL 3.2 Diabetes Module using quantitative methods. Further, previous investigators using the PedsQL 3.0 Diabetes Module have recommended a total score comprising all 28 items as most parsimonious based on factor analysis rather than the a priori five-scale structure, given the lower internal consistency reliability of some of the a priori scales (13). Nevertheless, a total score combines both diabetes symptoms and diabetes management items into one unitary summary score, which may not be the most accurate and precise representation of the constructs manifested by the items.

Consequently, the objective of the current study was to describe the feasibility, internal consistency reliability, construct validity, and minimal clinically important difference (MCID) scores of the 33-item PedsQL 3.2 Diabetes Module for children, adolescents, and young adults with type 1 diabetes from a 10-site national field test study, designating a hypothesized two-factor structure comprising a Diabetes Symptoms Summary Score and Diabetes Management Summary Score as two new summary scores representing the constructs measured by the items.

RESEARCH DESIGN AND METHODS

Participants and Settings

Patients aged 2–25 years with type 1 diabetes were recruited from 10 clinical sites in the U.S. (see Supplementary Data). A total of 656 families participated (Table 1). Data collection for the field test took place between July 2015 and June 2017. Parental informed consent and patient assent/consent (when age appropriate) were obtained. The research protocol was approved by the institutional review board at each site.

Measures

PedsQL 3.2 Diabetes Module

The 33-item PedsQL 3.2 Diabetes Module is a diabetes-specific HRQOL instrument consisting of five a priori scales measuring Diabetes Symptoms (15 items), Treatment Barriers (5 items), Treatment Adherence (6 items), Worry (3 items), and Communication (4 items). Cognitive interviewing techniques were used to add, delete, and/or revise the items of the existing PedsQL 3.0 Diabetes Module as needed based on individual interviews with children, adolescents, and young adults with type 1 diabetes (12). In addition to rewording some items for greater clarity based on the cognitive interviews, 7 new items were added and 2 items deleted from the 28-item PedsQL 3.0 Diabetes Module resulting in 33 items, with the recall period changed from 1 month to 7 days based on patient feedback (12). Specifically, we added the following four new diabetes symptoms items: "I feel like I need to throw up," "I go high," "I feel dizzy," and "I feel weak." We reworded "I feel tired or fatigue" to "I feel tired" as "fatigue" was not well understood by all patients. We reworded "I feel irritable" to "I feel cranky or grumpy" because "cranky or grumpy" was better understood by most patients. The only difference between the children, teen, and the young adult versions for the 15 diabetes symptoms was the item, "I have stomachaches." For children, the item was worded as, "I have tummy aches." For diabetes management, the items "I am embarrassed by my diabetes treatment" and "I worry about going high" were added and "I worry about whether or not my medical treatments are working" was deleted based on patient input. "It is hard for me to wear my id bracelet" was deleted as it was no longer deemed relevant. A double-barreled question (measuring two constructs), "It hurts to prick my finger or give insulin shots," was reworded into two separate single construct items, "It is hard for me to take glucose tests" and "It is hard for me to take insulin shots," resulting in an additional item. The item "It is hard for me to stick to my diabetes care plan" was reworded to "It is hard for me to do everything I need to do to care for my diabetes" to improve clarity based on patient feedback as "diabetes care plan" was not terminology used by most patients. The item "It is hard for me to exercise" was reworded for child self-report to "It is hard for me to play or do sports" and for adolescent self-report to "It is hard for me to exercise or do sports." For young adults, this item reads, "It is hard for me to exercise." These changes were made to be more relevant to children and adolescents based on their input. For the item, "It is hard for me to keep track of carbohydrates or exchanges," the words "or exchanges" were deleted as "exchanges" was not well understood. For the item, "It is hard for me to eat snacks," the phrase "when I go low" was added as patients expressed the need for this clarity. The item now reads, "It is hard for me to snack when I go low." For ages 2–7 years, the item regarding worrying about long-term complications from diabetes is not included for both patient self-report and parent

This article contains Supplementary Data online at http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc17-2707/-/DC1.

M.A.F. is now at the Institute for Brain Protection Sciences, Johns Hopkins All Children's Hospital, St. Petersburg, FL. E.M.D. is now at the University of Oklahoma Health Sciences Center, Oklahoma City, OK.

**A list of the Pediatric Quality of Life Inventory 3.2 Diabetes Module Testing Study Consortium sites and principal investigators is in the Supplementary Data online.*

Table 1—Demographic and clinical characteristics of participants

N	656
Age, years	14.25 ± 3.6
Sex	
Male	319 (48.6)
Female	337 (51.4)
Race/ethnicity	
White non-Hispanic	400 (61.3)
Hispanic	93 (14.2)
Black non-Hispanic	98 (15.0)
Asian/Pacific Islander	13 (2.0)
Other	49 (7.5)
Parent education, mothers	
Less than high school graduate	39 (6.4)
High school graduate	73 (12.0)
Some college or certification course	189 (31.0)
College graduate	193 (31.6)
Graduate or professional degree	114 (18.7)
Parent education, fathers	
Less than high school graduate	46 (8.1)
High school graduate	111 (19.6)
Some college or certification course	149 (26.4)
College graduate	143 (25.3)
Graduate or professional degree	112 (19.8)
Diabetes duration, years	5.4 ± 3.9
HbA_{1c}, % (mmol/mol)	8.8 ± 1.9 (73)
BMI, kg/m^2	22.5 ± 6.4
BMI percentile	66.5 ± 27.0
Insulin pump, % yes	335 (51.1)
Continuous glucose monitoring, % yes	201 (30.6)

Data are *n* (%) or mean ± SD, unless otherwise stated. Subgroup sample sizes may differ given missing data.

proxy report as it is a concept too difficult for the younger age-groups to understand. Diabetes symptoms and management concerns elicited during the cognitive interviews were remarkably consistent across the age-groups tested (12). A concept tracking matrix showing the changes between revisions, age-appropriate wording differences, and the final items of the new 33-item PedsQL 3.2 Diabetes Module have been published in a content validity study (12). The items for teen self-report are listed in Table 2.

The PedsQL 3.2 Diabetes Module is composed of parallel patient self-report and parent proxy report formats for ages 5–25 years and a parent proxy report format for ages 2–4 years. Patient self-report forms are specific for ages 5–7, 8–12, 13–18, and 18–25 years. Parent proxy report forms are specific for ages 2–4 (toddler), 5–7 (young child), 8–12 (child), 13–18 (adolescent), and 18–25 (young adult) years and assess patient's and parent's perceptions of the patient's diabetes-specific symptoms and management problems. One adult from each family (70.3% mothers, 14.3% fathers, 2.9% grandparents, 1.1% guardians, 3.8% other, 7.6% missing) completed the proxy report version for the current study. The items for each of the forms are essentially identical, differing in developmentally appropriate language, or first or third person tense. The instructions ask how much of a problem each item has been during the past 7 days. The grammar and syntax of the new items are structurally equivalent to those in the existing PedsQL item bank (12). The 5-point Likert-type response scale is the same as the existing PedsQL 3.0 Diabetes Module, with items reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), so that lower scores demonstrate more diabetes symptoms and management problems and, hence, lower diabetes-specific HRQOL. Summary scores are computed as the sum of the items divided by the number of items answered (this accounts for missing data). If more than 50% of the items in the scale are missing, the summary score is not computed (14). This accounts for the differences in sample sizes for Diabetes Symptoms and Diabetes Management Summary Scores reported in the tables. Although there are other strategies for imputing missing values, this computation is consistent with previous PedsQL peer-reviewed publications, as well as other well-established HRQOL measures (15).

PedsQL 4.0 Generic Core Scales

The 23-item PedsQL 4.0 Generic Core Scales encompass Physical Functioning (8 items), Emotional Functioning (5 items), Social Functioning (5 items), and School Functioning (5 items) (16). To create the Total Scale Score, the mean is computed as the sum of the items divided by the number of items answered in the Physical, Emotional, Social, and School Functioning Scales. The Total Scale Score measures overall generic HRQOL (16). Higher scores indicate better HRQOL.

PedsQL Family Information Form

Caregivers or older patients completed the PedsQL Family Information Form, which contains demographic information including the child's date of birth, sex, and race/ethnicity (16).

HbA_{1c}

HbA_{1c} values were measured at each data collection site using standard point-of-care methods (e.g., DCA Vantage Analyzer) and not at a central laboratory. The most recent HbA_{1c} value from the patient's medical record was used.

BMI

BMI values were calculated from height and weight measures at each data collection site. BMI percentile values were calculated using the Centers for Disease Control and Prevention scoring algorithms (17).

Statistical Analysis

A principal component factor analysis with promax rotation of the items was initially conducted with all 33 items to evaluate the factor structure of the PedsQL 3.2 Diabetes Module. We hypothesized that the diabetes symptoms and diabetes management items would represent two different factors (constructs) configured as two new summary scores representing the Diabetes Symptoms Summary Score and the Diabetes Management Summary Score. Based on recommendations from the measurement literature, we included items with a factor loading of 0.30 or greater (18).

Table 2—Factor loadings of the 33 items of the PedsQL 3.2 Diabetes Module for patient self-report

		Factor structure								
Scales	Items	1	2	3	4	5	6	7	Diabetes symptoms	Diabetes management
Diabetes Symptoms	I feel hungry							**0.80**	**0.39**	
	I feel thirsty							**0.85**	**0.53**	
	I have to go to the bathroom too often	**0.30**						**0.53**	**0.57**	
	I have stomachaches	**0.71**							**0.62**	
	I have headaches	**0.81**							**0.64**	
	I feel like I need to throw up	**0.77**							**0.60**	
	I go "low"				**0.79**				**0.57**	
	I go "high"					**0.36**			**0.37**	
	I feel tired	**0.50**							**0.66**	
	I get shaky				**0.69**				**0.80**	
	I get sweaty				**0.47**				**0.77**	
	I feel dizzy	**0.40**			**0.55**				**0.75**	
	I feel weak				**0.52**				**0.70**	
	I have trouble sleeping	**0.60**							**0.45**	
	I get cranky or grumpy	**0.62**							**0.55**	
Treatment Barriers	It hurts to get my finger pricked						0.78			0.45
	It hurts to get insulin shots						0.77			0.65
	I am embarrassed by my diabetes treatment			0.79						0.77
	My parents and I argue about my diabetes care					0.34				0.46
	It is hard for me to do everything I need to do to care for my diabetes		0.53							0.74
Treatment Adherence	It is hard for me to take blood glucose tests		0.59				0.36			0.65
	It is hard for me to take insulin shots		0.53				0.43			0.72
	It is hard for me to exercise or do sports	0.32	0.50							0.35
	It is hard for me to keep track of carbohydrates		0.69							0.49
	It is hard for me to carry a fast-acting carbohydrate		0.82							0.46
	It is hard for me to snack when I go "low"		0.45		0.34					0.37
Worry	I worry about going "low"				0.39	0.79				0.31
	I worry about going "high"					0.90				0.43
	I worry about long-term complications from diabetes					0.73				0.52
Communication	It is hard for me to tell the doctors and nurses how I feel		0.61	0.36						0.70
	It is hard for me to ask the doctors and nurses questions		0.58	0.44						0.62
	It is hard for me to explain my illness to other people			0.71						0.60
	I am embarrassed about having diabetes			0.80						0.79

Factor loadings in boldface type represent diabetes symptoms items. All other factor loadings represent diabetes management items. Factor loadings less than 0.30 are not included. See text for details of Diabetes Symptoms Summary Score and Diabetes Management Summary Score.

Feasibility was determined from the percentage of missing values (19). Cronbach coefficient α was used to determine internal consistency reliability (20). Internal consistency reliabilities of 0.70 or greater are recommended for comparing patient groups, whereas an internal consistency reliability criterion of 0.90 is recommended for analyzing individual patient scores (21). Range of measurement was based on the percentage of scores at the extremes of the scaling range, that is, the maximum possible score (ceiling effect = percentage of scale scores at 100 [never a problem]) and the minimum possible score (floor effect = percentage of scale scores at 0 [almost always a problem]). Surveys with small floor or ceiling effects (1%–15%) are considered to meet acceptable measurement standards, whereas surveys with moderate floor or ceiling effects (>15%) are considered less precise in measuring constructs at the extremes of the scale (22).

The MCID was calculated using the SEM derived by multiplying the SD by the square root of $1 - \alpha$ (Cronbach α reliability coefficient) (23). This equation, $SEM = SD\sqrt{[1 - \alpha]}$, is a distribution-based methodology for determining the MCID and has been previously used to determine the MCID for the PedsQL 3.0 Diabetes Module (8), as well as other PedsQL modules (24). The SEM has been linked to the MCID, in which 1 SEM has demonstrated a strong correspondence to anchor-based individual change thresholds (25). The MCID is considered the smallest clinically meaningful change in a PRO score that can be detected with measurement precision

for the construct (latent variable) and not as a result of measurement error (8,24,26). The MCID has been defined as "the smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, either beneficial or harmful, and that would lead the patient or clinician to consider a change in the management" (27). Thus, the MCID provides evidence in support of the clinical interpretability of scale scores (24) and represents a change in scores that would be perceived as a clinically meaningful difference to patients and their parents (8).

The intercorrelations among the PedsQL 3.2 Diabetes Module Diabetes Symptoms Summary Score and the Diabetes Management Summary Score and PedsQL Generic Core Scales were used to examine construct validity (28). Based on the conceptualization of disease-specific symptoms as causal indicators of generic HRQOL (29), we hypothesized that greater diabetes symptoms and diabetes management problems would correlate with lower overall generic HRQOL. Pearson product-moment correlation coefficients effect sizes are designated as small (0.10), medium (0.30), and large (0.50) in magnitude (30). We also examined the associations between the Diabetes Symptoms Summary Score and the Diabetes Management Summary Score and age, sex, HbA_{1c}, BMI, BMI percentile, and time since diagnosis.

Intraclass correlation coefficients (ICCs) were used to determine agreement between patient self-report and parent proxy report (31). The ICC provides an index of absolute agreement as it takes into account the ratio between subject variability and total variability (32). ICCs are designated as $\leq$0.40 (poor to fair agreement), 0.41–0.60 (moderate agreement), 0.61–0.80 (good agreement), and 0.81–1.00 (excellent agreement). Statistical analyses were conducted using IBM SPSS (Armonk, NY).

RESULTS

Demographic and Clinical Characteristics

Table 1 contains the demographic and clinical characteristics of the participants. Supplementary Table 2 contains the number of participants for each age-group (n = 4, ages 2–4 years; n = 21, ages 5–7 years; n = 200, ages 8–12 years; n = 375, ages 13–18 years; n = 49, ages 19–25 years; missing age variable = 7).

Factor Analysis: Patient Self-report

Based on the item factor loadings from the principal components factor analysis, two summary scores emerged that differentiated the items into the latent constructs "diabetes symptoms" and "diabetes management." Specifically, as shown in columns 1–7 in Table 2, when all items were subjected to factor analysis, the a priori diabetes symptoms scale items loaded into subgrouping of items that were generally consistent with items measuring diabetes symptoms (demonstrating face validity), and the a priori scales measuring problems with diabetes management loaded into subgroupings of items that were generally consistent with items measuring diabetes management problems (demonstrating face validity).

To further support these two summary scores, we then conducted a principal components factor analysis designating a priori a two-factor structure. As shown in Table 2 in the columns labeled "Diabetes symptoms" and "Diabetes management," the resulting factor loadings indicated that the Diabetes Symptoms Summary Score and the Diabetes Management Summary Score represented two different constructs. Even though a further exploratory factor analysis of the Diabetes Symptoms Summary Score suggested that the items might be additionally grouped into subscales or "facets" (33) measuring hypoglycemia and hyperglycemia, we determined that the cross-loadings of some items did not warrant demarcating the items further. Factor analysis of the items in the Diabetes Management Summary Score suggested that the Worry Scale items loaded as the a priori Worry Scale, whereas the other items loaded in subscales or facets not consistent with the a priori scales. Accordingly, we determined that the Diabetes Management Summary Score was the most parsimonious scoring method for the diabetes management items.

Factor Analysis: Parent Proxy Report

It should be noted that the PedsQL 3.2 Diabetes Module was primarily designed to measure patient self-reported HRQOL. Nonetheless, parent proxy report is considered a necessary complement for patient self-report given that parents' perspectives may drive patient health care use, particularly for younger patients and those patients who cannot self-report. In this context, we also examined the parent proxy report factor loadings for the 33 items by conducting a principal components factor analysis designating a priori a two-factor solution. As shown in Supplementary Table 1, the two-factor solution for parent proxy report items is generally consistent with the two-factor solution for patient self-report.

Internal Consistency Reliability

Cronbach α internal consistency reliability coefficients for the Diabetes Symptoms and Diabetes Management Summary Scores are shown in Table 3. All patient self-report and parent proxy report summary scores approach, meet, or exceed the reliability criterion of 0.90 recommended for analyzing individual patient scores when combined across age-groups. As shown in Supplementary Table 2, when analyzing the individual age-groups, patient self-report for ages 5–7 years did not meet the 0.70 criterion for group comparisons, whereas patient

Table 3—PedsQL 3.2 Diabetes Module Summary Scores, reliability, percent floor and ceiling effects, and MCIDs

Diabetes Module Summary Scores	Items, *n*	Participants, *n*	Cronbach α	Mean	SD	% Floor	% Ceiling	MCID
Patient self-report								
Diabetes Symptoms	15	647	0.88	65.53	16.01	0.2	0.6	5.55
Diabetes Management	18	647	0.89	79.19	15.29	0.2	3.5	5.07
Parent proxy report								
Diabetes Symptoms	15	602	0.90	68.14	16.27	0.2	0.8	5.15
Diabetes Management	18	603	0.90	77.37	15.96	0.2	4.1	5.05

Lower scores demonstrate more diabetes symptoms and diabetes management problems and hence lower diabetes-specific HRQOL.

self-report for ages 8–25 years meet, approach, or exceed the 0.90 criterion.

Feasibility: Missing Item Responses

The percentage of missing item responses were 0.01% and 0.05% for patient self-report and parent proxy report, respectively.

Range of Measurement

Table 3 contains the percentage of scores at the extremes of the scaling range (floor and ceiling effects) for the Diabetes Symptoms and Diabetes Management Summary Scores. For patient self-report and parent proxy report, there were no significant floor effects (lower scores demonstrate more diabetes symptoms and diabetes management problems and hence lower diabetes-specific HRQOL) or ceiling effects (higher scores demonstrate less diabetes symptoms and management problems and hence higher diabetes-specific HRQOL).

Construct Validity

Table 4 shows the correlations between the Diabetes Symptoms and Diabetes Management Summary Scores with the PedsQL 4.0 Generic Core Scales and Summary Scores. The majority of the correlations demonstrate large effect sizes ($\geq$0.50) in magnitude (all $P < 0.001$), supporting construct validity.

We also examined the correlations between the Diabetes Symptoms and Diabetes Management Summary Scores. As anticipated, the Diabetes Symptoms and Diabetes Management Summary Scores were highly correlated (patient self-report $r = 0.63$, $P < 0.001$; parent proxy report $r = 0.62$, $P < 0.001$), similar to the correlations with the Generic Core Scales Total Scale Score. Even though the Diabetes Symptoms and Diabetes Management Summary Scores are significantly correlated, the data suggest that they are measuring distinct constructs as the percent variance accounted for (r^2) are relatively modest (patient self-report $r^2 = 0.40$ [40% of the variance]; parent proxy report $r^2 = 0.38$ [38% of the variance]). Thus, although it would be expected that diabetes symptoms would be associated with diabetes management, the percent variance accounted for in diabetes symptoms by diabetes management indicates that other factors are relevant in explaining the remaining variance in diabetes symptoms. Also of note, Diabetes Symptoms Summary Scores were significantly lower (worse) than Diabetes Management Summary Scores (patient self-report 65.53 vs. 79.19, respectively, $t[646] = -25.67$, $P < 0.001$; parent proxy report 68.14 vs. 77.42, respectively, $t[601] = -16.18$, $P < 0.001$), further supporting two summary scores rather than one unitary total score for all the items.

MCID Scores

Table 3 shows the MCID scores. These MCID values provide information on the clinical interpretability of the summary scores. For example, from Table 3, a patient self-reported Diabetes Symptoms Summary Score that changed greater than or equal to 5.55 is a numerical value indicating the smallest clinically meaningful change that can be detected. The other MCID values in Table 3 can be similarly interpreted.

Clinical and Demographic Variables Associations

Supplementary Table 3 contains the associations with clinical and demographic variables. HbA_{1c} was significantly correlated with the Diabetes Symptoms and Diabetes Management Summary Scores for both patient self-report and parent proxy report. BMI was not significantly correlated with the summary scores. BMI percentile was only significantly correlated with parent proxy reported Diabetes Symptoms and Diabetes Management Summary Scores. Time since diabetes diagnosis was not significantly associated with the summary scores. Age was not significantly correlated with the summary scores. Females demonstrated significantly lower (worse) summary scores than males for patient self-report and parent proxy report. Mothers proxy reported significantly worse Diabetes Symptoms Summary Scores for their children than fathers (68.03 vs. 73.60, respectively, $t[545] = -3.11$, $P < 0.01$), but no proxy-reported significant differences between mothers and fathers for Diabetes Management Summary Scores (77.86 vs. 78.82, respectively, $t[546] = -0.55$, $P > 0.05$) were demonstrated.

Parent/Child Agreement

The ICCs between patient self-report and parent proxy report were 0.51 and 0.47 for the Diabetes Symptoms and Diabetes Management Summary Scores, respectively ($P < 0.001$). These ICC values represent moderate agreement.

CONCLUSIONS

These analyses support the feasibility, internal consistency reliability, construct validity, and MCID of the PedsQL 3.2 Diabetes Module Diabetes Symptoms and Diabetes Management Summary Scores. The PedsQL 3.2 Diabetes Module represents a revised and updated version of the widely used PedsQL 3.0 Diabetes

Table 4—PedsQL 3.2 Diabetes Module Summary Scores intercorrelations with the PedsQL 4.0 Generic Core Scales and Summary Scores

	Generic Core Scales					
Diabetes Module Summary Scores	Total Scale Score	Physical Functioning	Psychosocial Summary	Emotional Functioning	Social Functioning	School Functioning
Patient self-report	82.11 ± 13.97 (n = 644)	86.92 ± 14.00 (n = 644)	79.53 ± 15.73 (n = 644)	77.54 ± 20.30 (n = 643)	88.81 ± 15.14 (n = 643)	72.45 ± 19.89 (n = 643)
Diabetes Symptoms	0.67	0.56	0.65	0.64	0.43	0.57
Diabetes Management	0.67	0.51	0.67	0.67	0.50	0.52
Parent proxy report	81.61 ± 15.51 (n = 598)	85.28 ± 18.04 (n = 598)	79.65 ± 16.81 (n = 598)	76.91 ± 20.81 (n = 598)	88.05 ± 16.82 (n = 598)	74.05 ± 21.81 (n = 595)
Diabetes Symptoms	0.66	0.51	0.65	0.61	0.50	0.54
Diabetes Management	0.64	0.45	0.65	0.63	0.52	0.49

Data are mean ± SD or r. All $P < 0.001$ based on Pearson product-moment correlations, which are designated as small (0.10), medium (0.30), and large (0.50) in magnitude. The Psychosocial Summary Score comprises the Emotional, Social, and School Functioning Scales.

Module and makes a significant contribution to the empirical literature by providing a contemporary measure of diabetes symptoms and diabetes management problems that are relevant to a broad age range.

It is essential to reemphasize that the previously recommended total score obscures the important conceptual distinctions between diabetes symptoms and diabetes management. In the current study, patients self-reported and parents proxy reported significantly lower (worse) Diabetes Symptoms Summary Scores than Diabetes Management Summary Scores. When reporting an averaged unitary total score, the differences between the diabetes symptoms versus diabetes management constructs are obfuscated as conceptually distinct PROs. Future studies should report the 15-item Diabetes Symptoms Summary Score and 18-item Diabetes Management Summary Score as separate outcomes in clinical trials and predictive analytics models rather than as one total score.

The MCIDs represent numeric values that indicate the magnitude of change in summary scores that are detectable by the patient and parent as a clinically meaningful difference in the constructs being measured and provide an important reference point that can be used in clinical research and practice (8,24). In the current study, the MCIDs for patient self-report and parent proxy report were 5.55 and 5.15 for the Diabetes Symptoms Summary Score and 5.07 and 5.05 for the Diabetes Management Summary Score, respectively. These MCIDs are comparable to the 5.27 for patient self-report and 4.54 for parent proxy report for the unitary total scale score as reported by Hilliard et al. (8) for the PedsQL 3.0 Diabetes Module in type 1 diabetes. Notably, the MCIDs for the 11-item version 3.0 Diabetes Symptoms Scale for patient self-report (7.56) and parent proxy report (5.81) from Hilliard et al. were somewhat larger and hence less precise than the current 15-item 3.2 version for the Diabetes Symptoms Summary Score. The MCIDs for the Diabetes Management Summary Scores for patient self-report and parent proxy report from the current study are considerably smaller and hence more precise than the individual 3.0 versions of the Treatment Barriers, Treatment Adherence, Worry, and Communication Scales reported in Hilliard et al. (8) for patient self-report (10.86, 9.99, 12.01, 7.53, respectively) and parent proxy report (10.57, 9.56, 8.52, 7.91, respectively), suggesting that the Diabetes Management Summary Score is a more precise MCID.

The current study has several strengths, including the rigorous methods used to construct the instrument, the relatively large overall sample size, the broad age range of participants, and the nationwide representation of the participants. Rates of insulin pump and continuous glucose monitor use in the sample are similar to published data from the T1D Exchange Clinic Registry (34), further supporting the representativeness of the sample. Limitations include the lack of information on families who chose not to participate, the lack of information on the percentage of participants who adhered to and met American Diabetes Association clinical guidelines, the absence of test/retest reliability, an unidentified standard window of time around the date that the youth completed the PedsQL 3.2 Diabetes Module and the most recent HbA_{1c} value was obtained, and the lack of information on the implementation/administration feasibility across clinic sites including recruitment rates, length of time for completion, and completion by paper/pencil or electronic version of the questionnaires. Additionally, construct validity was assessed through intercorrelations with generic HRQOL. Although an acceptable approach to validating a disease-specific HRQOL measurement instrument, future research should also include other standardized measures of psychosocial functioning. The sample size for ages 2–4 and ages 5–7 years were small, rendering the analyses of these two age-groups as preliminary. Additionally, patient self-report for ages 5–7 years did not attain conventional levels of internal consistency reliability, and additional research with larger sample sizes are needed for this age-group. Until that time, parent proxy report should be used for ages 5–7 years. An additional limitation was the lack of a central laboratory for HbA_{1c} measurement across the 10 sites, although the majority of the sites used a similar measurement approach. In testing conceptual or "mechanistic" models, one potential limitation of the Diabetes Management Summary Score is the inclusion of several constructs that may overlap with other measures in these models. For example, in testing conceptual models of treatment adherence using a specifically designed scale that measures diabetes adherence, it would be recommended to either separate out the items that measure this construct from the Diabetes Management Summary Score or simply to use only the Diabetes Symptoms Summary Score in the conceptual model. Finally, the items included in the PedsQL 3.2 Diabetes Module were developed through qualitative methods as recommended by the U.S. Food and Drug Administration, which included the patients' and their parents' perspective on the content of the items (12). This approach did not result in content covering newer diabetes technologies, as reflected in the lack of items on newer diabetes technologies in the Diabetes Management Summary Score items. When working with pediatric patients and families, it may be important to include other measures specifically focused on diabetes devices and technologies when administering the PedsQL.

Future studies using the Diabetes Symptoms and Diabetes Management Summary Scores should facilitate a more precise understanding of diabetes-specific HRQOL. When evaluating new and existing therapeutic interventions, the PedsQL 3.2 Diabetes Module Diabetes Symptoms and Diabetes Management Summary Scores may help clinicians and researchers identify individuals and patient groups with different diabetes-specific HRQOL profiles that may be used when individualizing patient-centered care. In sum, the Diabetes Symptoms and Diabetes Management Summary Scores represent standardized PROs of diabetes symptoms and diabetes management that may be useful for clinical research, clinical trials, and practice in children, adolescents, and young adults.

Acknowledgments. The investigators thank the following individuals for their involvement in participant recruitment, data collection, and/or data verification: Vincent Aguirre, Marta Pardo, and Morgan Drake (Texas A&M University); Natalie Beauregard and Cisco Pascual (Seattle Children's Research Institute); Nora Chokr and Marie Nader (University of California, San Francisco); Jacqueline Shea and Kylie

Benson (University of Colorado Denver); Lisa Keys and Elizabeth Dabrowski (Northwestern University Feinberg School of Medicine); Esti Iturralde and Bianca Agustin (Stanford University School of Medicine).

Funding and Duality of Interest. No funding was specifically designated for this field test study data collection effort or manuscript preparation. New item development and item modification of the existing PedsQL 3.0 Diabetes Module for the published item generation qualitative methods study for the PedsQL 3.2 Diabetes Module was previously funded by Eli Lilly and Co., Indianapolis, IN. J.W.V. holds the copyright and the trademark for the PedsQL and receives financial compensation from the Mapi Research Trust, which is a nonprofit research institute that charges distribution fees to for-profit companies that use the PedsQL. He did not receive funding from Eli Lilly and Co. for the current quantitative methods field test study. No other potential conflicts of interest relevant to this article were reported.

Author Contributions. J.W.V. was involved in the conception and design of the study, the writing of the first draft of the manuscript, the statistical analysis of the data, and the interpretation of the data. A.M.D., K.K.H., J.K.R., N.T.C., K.A.D., J.C.W., J.P.Y.-F., E.K.G., M.A.F., S.D.C., J.C.K., J.L.M., and D.P.W. were involved in the conception and design of the study, the acquisition of the data, the interpretation of the data, and the critical revision of the manuscript for important intellectual content. E.M.D. and R.W.H. were involved in the conception and design of the study, the interpretation of the data, and the critical revision of the manuscript for important intellectual content. All authors approved the final version of the manuscript. J.W.V. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

References

1. Mayer-Davis EJ, Lawrence JM, Dabelea D, et al.; SEARCH for Diabetes in Youth Study. Incidence trends of type 1 and type 2 diabetes among youths, 2002-2012. N Engl J Med 2017;376:1419–1429
2. Dabelea D, Mayer-Davis EJ, Saydah S, et al.; SEARCH for Diabetes in Youth Study. Prevalence of type 1 and type 2 diabetes among children and adolescents from 2001 to 2009. JAMA 2014;311:1778–1786
3. You WP, Henneberg M. Type 1 diabetes prevalence increasing globally and regionally: the role of natural selection and life expectancy at birth. BMJ Open Diabetes Res Care 2016;4:e000161
4. Gutacker N, Street A. Use of large-scale HRQoL datasets to generate individualised predictions and inform patients about the likely benefit of surgery. Qual Life Res 2017;26:2497–2505
5. Varni JW, Burwinkle TM, Jacobs JR, Gottschalk M, Kaufman F, Jones KL. The PedsQL in type 1 and type 2 diabetes: reliability and validity of the Pediatric Quality of Life Inventory Generic Core Scales and Type 1 Diabetes Module. Diabetes Care 2003;26:631–637
6. Anderson BJ, Laffel LM, Domenger C, et al. Factors associated with diabetes-specific health-related quality of life in youth with type 1 diabetes: the global TEENs study. Diabetes Care 2017;40:1002–1009
7. Lawrence JM, Yi-Frazier JP, Black MH, et al.; SEARCH for Diabetes in Youth Study Group. Demographic and clinical correlates of diabetes-related quality of life among youth with type 1 diabetes. J Pediatr 2012;161:201–7.e2
8. Hilliard ME, Lawrence JM, Modi AC, et al.; SEARCH for Diabetes in Youth Study Group. Identification of minimal clinically important difference scores of the PedsQL in children, adolescents, and young adults with type 1 and type 2 diabetes. Diabetes Care 2013;36:1891–1897
9. U.S. Food and Drug Administration. *Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.* Rockville, MD, U.S. Department of Health and Human Services, 2009
10. Lasch KE, Marquis P, Vigneux M, et al. PRO development: rigorous qualitative research as the crucial foundation. Qual Life Res 2010;19:1087–1096
11. Rothman M, Burke L, Erickson P, Leidy NK, Patrick DL, Petrie CD. Use of existing patient-reported outcome (PRO) instruments and their modification: the ISPOR good research practices for evaluating and documenting content validity for the use of existing instruments and their modification PRO task force report. Value Health 2009;12:1075–1083
12. Varni JW, Curtis BH, Abetz LN, Lasch KE, Piault EC, Zeytoonjian AA. Content validity of the PedsQL™ 3.2 Diabetes Module in newly diagnosed patients with type 1 diabetes mellitus ages 8-45. Qual Life Res 2013;22:2169–2181
13. Nansel TR, Weisberg-Benchell J, Wysocki T, Laffel L, Anderson B; Steering Committee of the Family Management of Diabetes Study. Quality of life in children with type 1 diabetes: a comparison of general and diabetes-specific measures and support for a unitary diabetes quality-of-life construct. Diabet Med 2008;25:1316–1323
14. Fairclough DL. *Design and Analysis of Quality of Life Studies in Clinical Trials: Interdisciplinary Statistics*. New York, Chapman & Hall/CRC, 2002
15. Varni JW, Limbers CA. The Pediatric Quality of Life Inventory: measuring pediatric health-related quality of life from the perspective of children and their parents. Pediatr Clin North Am 2009;56:843–863
16. Varni JW, Seid M, Kurtin PS. PedsQL 4.0: reliability and validity of the Pediatric Quality of Life Inventory version 4.0 generic core scales in healthy and patient populations. Med Care 2001;39:800–812
17. Kuczmarski RJ, Ogden CL, Guo SS, et al. 2000 CDC growth charts for the United States: methods and development. Vital Health Stat 11 2002;11:1–190
18. Floyd FJ, Widaman KF. Factor analysis in the development and refinement of clinical assessment instruments. Psychol Assess 1995;7:286–299
19. McHorney CA, Ware JE Jr, Lu JFR, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care 1994;32:40–66
20. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297–334
21. Nunnally JC, Bernstein IR. *Psychometric Theory*. New York, McGraw-Hill, 1994
22. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res 1995;4:293–307
23. 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
24. Varni JW, Bendo CB, Shulman RJ, et al.; Pediatric Quality of Life Inventory Gastrointestinal Symptoms Module Testing Study Consortium. Interpretability of the PedsQL Gastrointestinal Symptoms Scales and Gastrointestinal Worry Scales in pediatric patients with functional and organic gastrointestinal diseases. J Pediatr Psychol 2015;40:591–601
25. Wyrwich KW, Norquist JM, Lenderking WR, Acaster S; Industry Advisory Committee of International Society for Quality of Life Research (ISOQOL). Methods for interpreting change over time in patient-reported outcome measures. Qual Life Res 2013;22:475–483
26. Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. J Clin Epidemiol 2003;56:395–407
27. Schünemann HJ, Akl EA, Guyatt GH. Interpreting the results of patient reported outcome measures in clinical trials: the clinician's perspective. Health Qual Life Outcomes 2006;4:62
28. Pedhazur EJ, Schmelkin LP. *Measurement, Design, and Analysis: An Integrated Approach*. Hillsdale, NJ, Erlbaum, 1991
29. Fayers PM, Hand DJ. Factor analysis, causal indicators and quality of life. Qual Life Res 1997;6:139–150
30. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Hillsdale, NJ, Erlbaum, 1988
31. McGraw KO, Wong SP. Forming inferences about some intraclass correlation coefficients. Psychol Methods 1996;1:30–46
32. Bartko JJ. The intraclass correlation coefficient as a measure of reliability. Psychol Rep 1966;19:3–11
33. Costa PT Jr, McCrae RR. Domains and facets: hierarchical personality assessment using the revised NEO personality inventory. J Pers Assess 1995;64:21–50
34. Miller KM, Foster NC, Beck RW, et al.; T1D Exchange Clinic Network. Current state of type 1 diabetes treatment in the U.S.: updated data from the T1D Exchange Clinic Registry. Diabetes Care 2015;38:971–978