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

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OBJECTIVE — The Pediatric Quality of Life Inventory (PedsQL) is a modular instrument designed to measure health-related quality of life (HRQOL) in children and adolescents aged 2–18 years. The PedsQL 4.0 Generic Core Scales are child self-report and parent proxy-report scales developed as the generic core measure to be integrated with the PedsQL disease-specific modules. The PedsQL 3.0 Type 1 Diabetes Module was designed to measure diabetes-specific HRQOL.

RESEARCH DESIGN AND METHODS — The PedsQL Generic Core Scales and Diabetes Module were administered to 300 pediatric patients with type 1 or type 2 diabetes and 308 parents.

RESULTS — Internal consistency reliability for the PedsQL Generic Core Total Scale score ($\alpha = 0.88$ child, 0.89 parent-report) and most Diabetes Module scales (average $\alpha = 0.71$ child, 0.77 parent-report) was acceptable for group comparisons. The PedsQL 4.0 distinguished between healthy children and children with diabetes. The Diabetes Module demonstrated intercorrelations with dimensions of generic and diabetes-specific HRQOL.

CONCLUSIONS — The results demonstrate the reliability and validity of the PedsQL in diabetes. The PedsQL may be used as an outcome measure for diabetes clinical trials and research.

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Health-related quality of life (HRQOL) is an essential health outcome in clinical trials and health care (1–3). The most widely used disease-specific HRQOL measure for diabetes is the Diabetes Quality of Life (DQOL) measure developed for use in the Diabetes Control and Complications Trial (4). With the exception of a modified version for children aged 11 years and older (5), the DQOL has been primarily used in adults (6).

The Pediatric Quality of Life Inventory (PedsQL) measurement model (7) was designed to integrate the merits of generic and disease-specific instruments. The PedsQL 4.0 Generic Core Scales distinguish between healthy children and pediatric patients with acute or chronic health conditions (8), and they have demonstrated sensitivity, responsiveness, and an impact on clinical decision-making (9,10). The PedsQL 3.0 Type 1 Diabetes Module was developed to measure disease-specific HRQOL for type 1 diabetes. Although there are instruments that measure HRQOL in type 1 diabetes (6), we were not able to find a multidimensional instrument that assessed the broad age range of 2–18 years with both child self-report and parent proxy-report.

This study investigates the measurement properties of the PedsQL Generic Core Scales in type 1 and type 2 diabetes and the Diabetes Module in type 1 diabetes.

RESEARCH DESIGN AND METHODS

Diabetes sample

Participants were children aged 5–18 years ($n = 300$) and parents of children aged 2–18 years ($n = 308$) diagnosed with type 1 or type 2 diabetes, with 331 families accrued overall. For 279 children aged 5–18 years, both child self-report and parent proxy-report were available. Participant characteristics are shown in Table 1.

Healthy sample

Participants were healthy children and their parents from the PedsQL 4.0 field test (8). The demographics are described in Varni et al. (8). This healthy sample was younger (mean age 12.19 vs. 14.19 years) and represented fewer African-American (2.9 vs. 5.2%) and Asian/Pacific Islander

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Abbreviations: DQOL, Diabetes Quality of Life; HRQOL, health-related quality of life; PedsQL, Pediatric Quality of Life Inventory; SES, socioeconomic status.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

Table 1—*Participant characteristics*

	Type 1 diabetes (n = 237)			Type 2 diabetes (n = 91)			Total sample (n = 331)		
Characteristics	n	%	Mean ± SD	n	%	Mean ± SD	n	%	Mean ± SD
Administration									
Clinic	220	92.8	—	71	78.0	—	294	88.8	—
Telephone	17	7.2	—	20	22.0	—	37	11.2	—
Age (years)									
Total sample (range 2–18)	—	—	12.47 ± 4.04	—	—	15.11 ± 2.32	—	—	13.20 ± 3.83
Child-report only (range 5–18)	—	—	13.05 ± 3.51	—	—	15.11 ± 2.28	—	—	13.65 ± 3.33
Sex									
Male									
Total sample	104	43.9	—	44	48.4	—	149	45.0	—
Child-report only	91	42.9	—	42	48.3	—	134	44.7	—
Female									
Total sample	133	56.1	—	47	51.6	—	180	54.4	—
Child-report only	121	57.1	—	45	51.7	—	166	55.3	—
Ethnicity									
White/non-Hispanic	143	60.3	—	11	12.1	—	154	46.5	—
Hispanic/Latino	48	20.3	—	35	38.5	—	83	25.1	—
Black/non-Hispanic	13	5.5	—	22	24.2	—	35	10.6	—
Asian/Pacific Islander	11	4.6	—	17	18.7	—	29	8.8	—
American Indian/Alaskan Native	3	1.3	—	2	2.2	—	5	1.5	—
Other	17	7.2	—	3	3.3	—	20	6.0	—
SES*	—	—	45.36 ± 13.59	—	—	34.67 ± 13.32	—	—	42.72 ± 14.30
BMI†	—	—	21.96 ± 5.33	—	—	29.16 ± 7.60	—	—	23.89 ± 6.81
HbA_{1c}	—	—	8.7 ± 1.9	—	—	8.6 ± 2.4	—	—	8.64 ± 2.02
Language of form									
English	—	—	—	—	—	—	288	87.0	—
Spanish	—	—	—	—	—	—	41	12.4	—

Missing values for total sample include: sex, 2 case subjects (0.6%); ethnicity, 5 case subjects (1.5%); language of form, 2 case subjects (0.6%). χ^2 analysis indicated a nonsignificant relationship between sex and type of diabetes. *SES was based on the Hollingshead index. Value for total sample indicates middle class family SES. Tukey post hoc analysis indicates significant difference ($P < 0.001$) in SES between white/non-Hispanics (mean = 46.85) and Hispanic/Latinos (mean = 34.71). t test for independent samples indicates that the type 1 diabetes sample reported a higher SES (mean = 45.36) than the type 2 diabetes sample (mean = 34.67): t = 5.48, $P < 0.001$. †BMI was calculated as the child's weight divided by height squared. In adults, a BMI of ≥30 kg/m^2 indicates obesity. In our type 2 diabetes sample, 43% of children had a BMI of ≥30 kg/m^2. t-test for independent samples indicates that the type 1 diabetes sample had a significantly lower BMI than the type 2 diabetes sample (t = 9.20, $P < 0.001$). χ^2 analysis indicates a significant association between BMI and diabetes type (χ^2 = 27.26, $P < 0.001$), with a greater percentage of the type 2 diabetes sample (64.9%, standardized residual = 3.5) reporting a BMI score above the 95th percentile.

(1.2 vs. 4.1%) children and more Hispanic children (27.3 vs. 12.3%) than the diabetes sample.

Measures

The PedsQL 4.0 Generic Core Scales. The 23-item PedsQL 4.0 Generic Core Scales encompass: *1*) physical functioning (8 items), *2*) emotional functioning (5 items), *3*) social functioning (5 items), and *4*) school functioning (5 items). They were developed through focus groups, cognitive interviews, pretesting, and field testing measurement development protocols (7,8).

Child self-report includes ages 5–18 years, and parent proxy-report includes ages 2–18 years. The items for each form are essentially identical. The instructions ask how much of a problem each item has been during the past 1 month. A five-point response scale is used (0 = never a problem, 4 = almost always a problem). Items are reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, and 4 = 0), so that higher scores indicate better HRQOL. Scale scores are computed as the sum of the items divided by the number of items answered. If >50% of the items in the scale are missing, the scale score is not computed (11). After imputing missing values, 99% of child respondents and 98% of parent respondents were included in the scale score analyses. The physical health summary score (eight items) is the same as the physical functioning subscale. The psychosocial health summary score (15 items) is computed as the sum of the items divided by the number of items answered in the emotional, social, and school functioning subscales.

The PedsQL 3.0 Type 1 Diabetes Module. The 28-item multidimensional PedsQL 3.0 Diabetes Module encompasses five scales: *1*) diabetes symptoms (11 items), *2*) treatment barriers (4 items), *3*) treatment adherence (7 items), *4*) worry (3 items), and *5*) communication (3 items). The format, instructions, Likert-type response scale, and scoring method are identical to the PedsQL 4.0, with higher scores indicating fewer symptoms or problems. The PedsQL 3.0 Diabetes Module development consisted of a review of the literature, patient and parent focus groups and individual focus interviews, item generation, cognitive interviewing, pretesting, and subsequent field testing (12–14).

PedsQL Family Information Form. The Family Information Form contains the demographic information required to calculate the Hollingshead socioeconomic status (SES) index (15).

Procedure

Clinic assessment. Subjects were identified at the two sites when they presented for clinic. Written parental informed consent and child assent were obtained. Parents and children completed the PedsQL separately. A research assistant administered the PedsQL for children aged 5–7 years and was available to assist the self-administered instrument for ages 8–18 years.

Telephone assessment. Patients identified by their physician as meeting inclusion requirements were sent a letter from their physician. The letter included an 800 number that the family could call if they did not want to participate. A week after the letter was sent, a research assistant called the family and obtained verbal consent from the primary caregiver. Another research assistant on the telephone line witnessed the verbal consent. The questionnaires were read individually to the parent and child verbatim, and the answers were recorded. These research protocols were approved by the institutional review boards at each site.

Statistical analysis

Feasibility was determined from the percentage of missing values (16). Internal consistency reliability was determined by Cronbach's α-coefficient (17). Scales with reliabilities of ≥0.70 are recommended for comparing patient groups, whereas a criterion of 0.90 is recommended for analyzing individual patient scale scores (18,19).

Construct validity was determined using the known-groups method. The known-groups method compares scale scores across groups known to differ in the health construct being investigated. PedsQL 4.0 Generic Core Scales scores in groups differing in known health condition (healthy children and children with type 1 or type 2 diabetes) were computed (20,21) using *t* tests and one-way ANOVA. We hypothesized that: *1*) healthy children would report higher PedsQL 4.0 scores (better HRQOL) than patients with diabetes based on previous PedsQL 4.0 findings with other pediatric chronic health conditions (8–10,22). ANOVAs were conducted to examine whether there were differences in PedsQL 4.0 scores among children with type 1 or type 2 diabetes and healthy children.

Construct validity was further examined through an analysis of the intercorrelations among the PedsQL 4.0 Generic Core Total Scale score with the PedsQL 3.0 Diabetes Module scales scores. Computing the intercorrelations among scales provides initial information on the construct validity of an instrument (19). We hypothesized that: 2) higher scores on the diabetes symptom scale (fewer symptoms) would be correlated with higher Generic Core Total Scale scores, based on the conceptualization of disease-specific symptoms as causal indicators of HRQOL, (1) and previous PedsQL 4.0 findings (9,22); *3*) higher scores on the treatment barriers and treatment adherence scales (fewer problems with barriers and adherence) would be correlated with higher Generic Core Total Scale scores, based on the conceptualization that treatment adherence is associated with better symptom control and, consequently, better HRQOL (23); *4*) higher scores on the treatment barriers and treatment adherence scales would be correlated with higher scores on the diabetes symptom scale based on the treatment adherence literature (24,25); *5*) higher scores on the worry and communication scales (less worry and better communication, respectively) would be correlated with higher Generic Core Total Scale scores, based on previous PedsQL disease-specific module studies (9,22). Intercorrelations were expected to demonstrate medium to large effect sizes (1). Correlation effect sizes are designated as small (0.10), medium (0.30), and large (0.50) (26). Finally, we explored whether the PedsQL 4.0 scores would be different in children with type 1 or type 2 diabetes, and whether HbA_{1c} was related to HRQOL. Parent-child intercorrelations were computed to examine cross-informant variance. Response equivalence has been demonstrated across language and mode of administration (8); therefore, responses were pooled.

RESULTS

Missing item responses

For PedsQL 4.0 child self-report and parent proxy-report, the percentage of missing item responses was 0.1 and 1.4%, respectively. For the Diabetes Module, the percentage of missing item responses was 1.4% for child self-report and 3.6% for parent proxy-report.

Means and standard deviations

Table 2 presents the means and SDs of the PedsQL Generic Core Scales for children with diabetes and healthy children (8) and for the type 1 Diabetes Module.

Internal consistency reliability

α-Coefficients for the PedsQL across ages 2–18 years are presented in Table 2. Most child self-report scales and parent proxy-report scales exceeded the reliability standard of 0.70 (18). The PedsQL 4.0 total score across the ages approached the reliability criterion of 0.90 recommended for analyzing individual patient scores (18,19). Child self-report for the Diabetes Module exceeded the reliability standard of 0.70 for the diabetes symptoms scale and the communication scale, and it was in the 0.63–0.66 range for the other scales. All parent proxy-report scales except one exceeded the 0.70 standard.

Construct validity

Table 2 demonstrates the comparisons between the PedsQL Generic Core Scales for healthy children and children with diabetes as a group across ages 2–18 years. For child self-report, there was a significant difference between healthy children and children with diabetes for all scales except physical functioning and social functioning. For parent proxy-report, there was a significant difference between healthy children and children with diabetes on all scales. Tables 3 and 4 display the one-way ANOVAs comparing healthy children with children with type 1 and type 2 diabetes using the PedsQL Generic Core Scales for ages 8–18 years (matched to the age range for patients with type 2 diabetes). For all scales except physical functioning and social functioning, children with type 1 diabetes reported lower HRQOL than healthy children. For all scales except physical functioning, children with type 2 diabetes reported lower HRQOL than healthy children. Children with type 2 diabetes also reported lower generic HRQOL scores than children with type 1 diabetes on the total scale score, psychosocial health, and school functioning. For all parent proxy-report scales, children with type 1 and type 2 diabetes were reported as manifesting lower ge-

Table 2—*Scale descriptives for PedsQL 4.0 Generic Core Scales child self-report and parent proxy-report and comparisons with healthy children scores*

Scale	Number of items	Type 1 and type 2 diabetes sample			Healthy sample		Difference	*t*
		n	Mean ± SD	α	*n*	Mean ± SD		
Generic Core Scales								
Child self-report								
Total score	23	300	80.37 ± 12.90	0.88	401	83.00 ± 14.79	2.63	−2.46*
Physical health	8	300	85.95 ± 13.34	0.76	400	84.41 ± 17.26	−1.54	1.28
Psychosocial health	15	300	77.34 ± 14.62	0.84	399	82.38 ± 15.51	5.04	−4.36†
Emotional functioning	5	300	72.37 ± 19.57	0.73	400	80.86 ± 19.64	8.49	−5.67†
Social functioning	5	300	85.63 ± 16.24	0.73	399	87.42 ± 17.18	1.79	−1.40
School functioning	5	297	74.20 ± 18.08	0.71	386	78.63 ± 20.53	4.43	−2.94‡
Parent proxy-report								
Total score	23	307	76.56 ± 14.10	0.89	717	87.61 ± 12.33	11.05	−12.57†
Physical health	8	307	81.99 ± 17.22	0.82	717	89.32 ± 16.35	7.33	−6.47†
Psychosocial health	15	307	73.61 ± 15.37	0.85	717	86.58 ± 12.79	12.97	−13.98†
Emotional functioning	5	307	69.08 ± 18.57	0.77	718	82.64 ± 17.54	13.56	−11.14†
Social functioning	5	305	81.03 ± 19.38	0.79	716	91.56 ± 14.20	10.53	−9.68†
School functioning	5	299	70.80 ± 19.39	0.73	611	85.47 ± 17.61	14.67	−11.42†
Diabetes module§								
Child self-report								
Diabetes symptoms	11	147	65.31 ± 15.79	0.81	—	—	—	—
Treatment barriers	4	146	73.72 ± 20.91	0.66	—	—	—	—
Treatment adherence	7	145	80.81 ± 15.50	0.66	—	—	—	—
Worry	3	145	71.54 ± 22.48	0.63	—	—	—	—
Communication	3	143	74.07 ± 25.08	0.77	—	—	—	—
Parent proxy-report								
Diabetes symptoms	11	158	63.96 ± 13.37	0.81	—	—	—	—
Treatment barriers	4	157	66.44 ± 19.99	0.68	—	—	—	—
Treatment adherence	7	158	76.74 ± 17.13	0.73	—	—	—	—
Worry	3	156	68.24 ± 24.26	0.81	—	—	—	—
Communication	3	156	64.90 ± 25.98	0.84	—	—	—	—

*$P < 0.05$; ‡$P < 0.01$; †$P < 0.001$. Values are for participants aged 2–18 years. Higher Generic Core values equal better health-related quality of life. §Diabetes Module values represent type 1 diabetes only. Higher type 1 Diabetes Module values equal less symptoms or problems. Cronbach's α-coefficient was used for total diabetes sample.

neric HRQOL than healthy children. Parents did not report any generic HRQOL differences between children with type 1 and type 2 diabetes.

The intercorrelations between the PedsQL Generic Core Scales total score and the Diabetes Module were in the medium-to-large effect size range, with the largest intercorrelations between the diabetes symptoms scale and the Generic Core total score (0.66 child-report, 0.54 parent-report). Intercorrelations among the other scales were consistent with the a priori hypotheses and ranged from 0.35 to 0.66. Parent-child intercorrelations for the PedsQL Generic Core Scales and Diabetes Module ranged from 0.28 to 0.47, with most in the medium effect size range.

HbA_{1c}

For a subset of children with type 1 and type 2 diabetes, HbA_{1c} values were available. For the type 1 sample ($n = 211$), correlations between the child self-report generic core and diabetes scales and HbA_{1c} levels revealed small-to-medium correlation effect sizes for Generic Core total score (-0.17, $P < 0.05$), psychosocial health (-0.20, $P < 0.01$), school functioning (-0.29, $P < 0.001$), treatment barriers (-0.27, $P < 0.01$), and treatment adherence (-0.20, $P < 0.05$). Correlations between parent proxy-report Generic Core and diabetes scales and HbA_{1c} levels also revealed small-to-medium correlation effect sizes for Generic Core total score (-0.22, $P < 0.01$), psychosocial health (-0.28, $P < 0.001$), emotional functioning (-0.18, $P < 0.05$), social functioning (-0.16, $P < 0.05$), school functioning (-0.34, $P < 0.001$), treatment barriers (-0.23, $P < 0.01$), and treatment adherence (-0.19, $P < 0.05$). There were no significant correlations between HbA_{1c} and PedsQL child self-report and parent proxy-report scales for the type 2 diabetes sample ($n = 70$).

CONCLUSIONS — This study presents the measurement properties for the PedsQL in type 1 and type 2 diabetes. The analyses support the reliability and validity of the PedsQL as a child self-report and parent proxy-report HRQOL measurement instrument for diabetes. The PedsQL is the only empirically validated pediatric HRQOL instrument to span this broad age range for child self-report and parent proxy-report while maintaining item and scale construct consistency.

Items on the PedsQL had minimal missing responses, suggesting that children and parents are able to provide

Table 3—*PedsQL 4.0 Generic Core Scales child self-report: one-way ANOVAs comparing healthy children and children with type 1 and type 2 diabetes*

Scale	*n*	Mean ± SD	Difference	df	*F*	*P*
Total score			a < c,* b < a,* b < c†	2,576	11.47	0.001
Type 1_a	191	81.94 ± 12.43				
Type 2_b	87	77.47 ± 13.72				
Healthy$_c$	301	84.88 ± 13.26				
Physical health				2,575	1.54	0.215
Type 1_a	191	87.46 ± 12.31				
Type 2_b	87	84.25 ± 13.69				
Healthy$_c$	300	86.29 ± 15.38				
Psychosocial health			a, b < c,† b < a*	2,576	20.13	0.001
Type 1_a	191	78.95 ± 14.33				
Type 2_b	87	73.83 ± 15.57				
Healthy$_c$	301	84.20 ± 14.10				
Emotional functioning			a, b < c†	2,576	21.45	0.001
Type 1_a	191	73.98 ± 19.87				
Type 2_b	87	68.33 ± 19.21				
Healthy$_c$	301	81.97 ± 18.60				
Social functioning			b < c‡	2,576	7.42	0.001
Type 1_a	191	87.16 ± 15.63				
Type 2_b	87	83.45 ± 17.42				
Healthy$_c$	301	90.30 ± 14.51				
School functioning				2,568	11.17	0.001
Type 1_a	190	75.99 ± 16.78	a < c,* b < a,* b < c†			
Type 2_b	86	69.59 ± 20.51				
Healthy$_c$	295	80.12 ± 19.23				

*$P < 0.05$, ‡$P < 0.01$, †$P < 0.001$ based on Tukey honestly significant difference post hoc analysis. These analyses were conducted for ages 8–18 years only, to make the type 1 diabetes, type 2 diabetes, and healthy sample contrast groups comparable in age. a, b, and c indicate the contrasts among the type 1 diabetic, type 2 diabetic, and healthy subjects, respectively.

good-quality data regarding the child's HRQOL. The PedsQL self-report and proxy-report internal consistency reliabilities generally exceeded the recommended minimum α-coefficient standard of 0.70 for group comparisons. Across the age ranges, the PedsQL 4.0 Generic Core Scales total score for both child self-report and parent proxy-report approached or exceeded an α of 0.90, recommended for individual patient analysis (18), making the total scale score suitable as a summary score for the primary analysis of HRQOL outcome in clinical trials and other group comparisons. The only exception was child self-report for 5–7 years of age, where the α was acceptable for group comparisons only. The physical health and psychosocial health summary scores are recommended for secondary analyses. The emotional, social, and school functioning subscales may be used to examine specific domains of functioning, with the caveat that until further testing is conducted, scales not achieving an $\alpha \geq 0.70$ should be used only for descriptive or exploratory analyses.

The PedsQL 3.0 Diabetes Module scales internal consistency reliabilities generally exceeded the recommended minimum α-coefficient standard of 0.70 for group comparisons for child self-report for ages 8–18 years and parent proxy-report for ages 2–18 years. For young-child self-report ages 5–7 years, only the treatment adherence scale met the 0.70 standard for group comparisons, whereas several of the other scales were in the 0.60 range. Although Cronbach's α internal consistency coefficients represent the lower bound of the actual reliability of a measurement instrument, and thus are a conservative estimate of actual reliability (27), until further testing is conducted, scales that did not achieve the standard of 0.70 should be used only for descriptive or exploratory analyses. For the purposes of a clinical trial, the PedsQL 3.0 Diabetes Module diabetes symptom scale in combination with the PedsQL 4.0 Generic Core Scales would provide an integrative HRQOL measurement model, with the advantages of both generic and diabetes-specific scales and with known reliability and validity across a wide age range.

The cross-informant variance observed in the parent/child-report supports the need to measure the perspectives of child and parent informants in evaluating pediatric HRQOL. The use of parent proxy-report to estimate child HRQOL may be necessary when the child is either unable or unwilling to complete the HRQOL measure, or when young child self-report scale reliabilities do not achieve the 0.70 standard. The present findings have several potential limitations. Information on nonparticipants was not available, which may limit the generalizability of the findings. Test-retest reliability was not conducted; however, test-retest reliability may be less useful than internal consistency reliability in HRQOL instrument development, given that short-term fluctuations are highly likely in a health condition in which external factors, such as disease and treatment variables, are expected to influence functioning. The method for testing construct validity used the known-groups approach. Additional

Table 4—*PedsQL 4.0 Generic Core Scales parent proxy-report: one-way ANOVAs comparing healthy children and children with type 1 and type 2 diabetes*

Scale	*n*	Mean ± SD	Difference	df	*F*	*P*
Total score			a, b < c*	2,641	53.93	0.001
Type 1_a	189	76.61 ± 14.29				
Type 2_b	79	74.36 ± 14.09				
Healthy$_c$	376	87.20 ± 13.23				
Physical health			a, b < c*	2,641	13.18	0.001
Type 1_a	189	82.32 ± 17.99				
Type 2_b	79	80.45 ± 15.40				
Healthy$_c$	376	88.76 ± 17.22				
Psychosocial health			a, b < c*	2,641	68.61	0.001
Type 1_a	189	73.54 ± 15.36				
Type 2_b	79	71.07 ± 16.06				
Healthy$_c$	376	86.37 ± 13.81				
Emotional functioning			a, b < c*	2,642	41.94	0.001
Type 1_a	189	68.51 ± 19.35				
Type 2_b	79	69.30 ± 18.39				
Healthy$_c$	377	82.73 ± 19.16				
Social functioning			a, b < c*	2,638	41.95	0.001
Type 1_a	188	81.89 ± 19.61				
Type 2_b	78	76.61 ± 20.71				
Healthy$_c$	375	92.24 ± 14.12				
School functioning			a, b < c*	2,628	46.88	0.001
Type 1_a	188	70.22 ± 19.03				
Type 2_b	77	67.68 ± 20.38				
Healthy$_c$	366	84.17 ± 18.51				

*$P < 0.001$ based on Tukey honestly significant difference post hoc analysis. These analyses were conducted for ages 8–18 years only, to make the type 1 diabetes, type 2 diabetes, and healthy sample contrast groups comparable in age. a, b, and c indicate the contrasts among the type 1 diabetic, type 2 diabetic, and healthy subjects, respectively.

methods for testing construct validity include correlating the instrument with other standardized measures of functioning. There were higher PedsQL 4.0 scores for the telephone versus clinic mode of administration in type 2 diabetes, indicating social desirability responding, consistent with the survey research literature (28). Although including these higher values for the 20 patients with type 2 diabetes is a conservative test of our known-groups hypothesis, this finding suggests that the telephone mode of administration for type 2 diabetes may result in higher HRQOL scores. In the type 1 diabetes sample, there was no mode of administration differences, consistent with the field test (8). Finally, the healthy sample was somewhat younger than the diabetes sample, with several race/ethnic differences. The differences in generic HRQOL between type 1 and type 2 diabetes may be attributed to differences in participant characteristics. In type 2 diabetes, patients were more likely to be overweight, had lower SES, and were from ethnic groups in which health disparities have been documented. Other causes of these HRQOL differences should be a focus of future research.

Finally, the small-to-medium correlation effect sizes between perceived HRQOL and HbA_{1c} are consistent with the broader literature across diseases, as succinctly summarized by McHorney (29, p. III58):

> "QOL scores correlate modestly at best with clinical outcomes. This finding suggests that clinical and human function are relatively independent. It does not imply that one or the other is inherently superior or correct. They simply measure different things, and using both will likely yield more information than any set alone."

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