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Quality of life of children and adolescents from São Paulo: reliability and validity of the Brazilian version of the Pediatric Quality of Life Inventory™ version 4.0 Generic Core Scales

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Abstract

Objectives: To evaluate the reliability and validity of the Brazilian version of the Pediatric Quality of Life Inventory™ (PedsQL™ 4.0) Generic Core Scales and measure the quality of life of healthy children and adolescents and patients with rheumatic diseases.

Methods: We followed the translation methodology proposed by the developer of the original English version of the PedsQL™ 4.0. The instrument was administered by interviews in two groups: 240 apparently healthy children and adolescents from São Paulo (SP, Brazil) and 105 patients with chronic rheumatic diseases matched by age, as well as their respective parents or caregivers. The parent proxy-report was administered to the children's parents or caregivers separately on the same day.

Results: Cronbach's alpha values were between 0.6 and 0.9 for all dimensions, demonstrating adequate internal consistency. Patients with rheumatic diseases reported significantly lower PedsQL™ scores on all dimensions when compared to the healthy control group ($p < 0.0001$). Construct validity of the Brazilian Portuguese version of the PedsQL™ 4.0 was also confirmed. Parent proxy-report of patients with rheumatic diseases highly correlated with child self-report for physical functioning ($r = 0.77$, $p < 0.001$) and school functioning ($r = 0.73$, $p < 0.001$). Lower correlations were observed for emotional and social functioning ($r = 0.40$ and 0.59, respectively, $p < 0.001$).

Conclusions: The tool demonstrated reliability, validity, and the administration was fast and easy. Quality of life in patients with rheumatic diseases was significantly lower than in the healthy control group, supporting the necessity of a comprehensive approach to rheumatic disease management, focused on the psychosocial dimensions.

J Pediatr (Rio J). 2008;84(4):308-315: Quality of life, questionnaire, PedsQL™, validation, translation, functional status.

Introduction

Health-related quality of life (HRQOL) has been increasingly acknowledged as an essential health outcome measure in pediatric medicine. The last decade has experienced a dramatic increase in the development and utilization of pediatric HRQOL measures in an effort to comprehensively assess patient health and well-being.[1,2] A HRQOL instrument must

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be multidimensional, consisting at the minimum of the physical, psychological (which includes emotional and cognitive), and social health dimensions delineated by the World Health Organization (WHO, 1948).[3]

HRQOL measurement has emerged as an important health outcome in clinical trials, clinical practice improvement strategies, and healthcare service research and evaluation. HRQOL measurement is essential in identifying children with the greatest needs, while simultaneously demonstrating the cost advantages of providing timely, targeted interventions to address those needs.[4]

Pediatric rheumatic diseases have been shown to cause a negative impact on the HRQOL of children and adolescents. Rheumatic diseases in childhood can persist over many years and patients may experience disability and dysfunction in adult life. While physical functioning is compromised initially, disease and treatment also negatively impacts emotional, social and school functioning.[5-9]

The Pediatric Quality of Life Inventory™ (PedsQL™) measurement model was designed as a modular approach to measuring pediatric HRQOL, developed to integrate the relative merits of generic and disease-specific approaches.[10] The PedsQL™ 4.0 Generic Core Scales includes child self-report for ages 5-18 and parent proxy-report for ages 2-18.[11] The American-English version of the PedsQL™ 4.0 Generic Core Scales has been previously demonstrated to be a feasible, reliable and valid 23-item HRQOL measure for pediatric patients with chronic health conditions and healthy school and community populations, [2,4,12-17] including pediatric rheumatology.[18]

The PedsQL™ 4.0 has been cross-culturally validated in a growing number of countries, including Australia,[19] Germany,[20] United Kingdom,[21] Norway,[22] Finland[23] and Japan (short-form version).[24] The translation and cross-cultural adaptation of a translated instrument requires not only the commonly accepted method of forward and backward translation, but also a validation process which includes field testing and analysis to estimate reliability and validity of the translated instrument in the target country.[25-27]

The objectives of the present study are: 1) to translate and validate the PedsQL™ 4.0 Generic Core Scales into the Portuguese language version applicable to the Brazilian culture, and 2) to measure the HRQOL of a group of children with rheumatic diseases followed in the Pediatric Rheumatology Unit of the Universidade Federal de São Paulo/Escola Paulista de Medicina (EPM/Unifesp), São Paulo (Brazil), in comparison to a match control sample of healthy children in São Paulo.

Methods

We followed the methodology commonly used in the translation and validation of HRQOL instruments,[25-28] according to the following steps:

Step 1. Independent translation of the original American-English version of the PedsQL™ 4.0 for the Portuguese language by three bilingual researchers (D.A.K., C.A.L., R.M.C.), followed by discussion by a translation committee with the intention to combine the three versions translated into a consensus version. In this stage the researchers strived for linguistic and conceptual equivalence.

Step 2. The forward translated version in Portuguese was then back-translated into American English by two bilingual translators. This version was subsequently sent to the PedsQL™ project team in the USA for feedback.

Step 3. Cognitive Interviewing. In this phase, the translated version was administered to a group of patients with rheumatic diseases followed in our clinic and to their parents. Five children and parents of each age range were interviewed (2-4 years [parents only], 5-7 years, 8-12 years and 13-18 years), following the PedsQL™ cognitive interviewing methodology. The aim of this phase was to modify any translated items or instructions leading to misunderstandings on the part of the children or their parents.

Step 4. In the field test phase the questionnaires were administered to a larger group of patients, stratified by age range, and to their parents. The PedsQL™ 4.0 was also administered to a control group of healthy children and their parents, selected in three different areas of São Paulo. These children and adolescents and their parents were interviewed in schools and as part of a vaccination campaign in the city.

Inclusion criteria were patients between 2 and 18 years, diagnosis of rheumatic disease according to current criteria,[5,7,8,19,29] absence of other physical and/or mental comorbidities and presence of at least one parent or caregiver in the consultation. Inclusion criteria for the healthy control children were age between 2 and 18 years, absence of chronic or acute illnesses in the last 30 days before the interview and presence of at least one parent on the day the questionnaire was applied. Demographic and socioeconomic data were collected according to criteria of the Brazilian Association of Research Companies (ABEP).[30]

Measures

The Pediatric Quality of Life Inventory™ Version 4.0

The 23-item PedsQL™ 4.0 Generic Core Scales encompass: 1) physical functioning (eight items), 2) emotional functioning (five items), 3) social functioning (five items), and 4) school functioning (five items). They were developed through focus groups, cognitive interviews, pretesting, and field testing measurement development protocols.[10,11] The instrument takes approximately 5 minutes to complete.[11]

The PedsQL™ 4.0 Generic Core Scales are comprised of parallel child self-report and parent proxy-report formats. Child self-report includes ages 5-7, 8-12, and 13-18 years.

Parent proxy-report includes ages 2-4 (toddler), 5-7 (young child), 8-12 (child), and 13-18 (adolescent), and assesses parent's perceptions of their child's HRQOL. 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 1 month. A five-point response scale is utilized across child self-report for ages 8-18 and parent proxy-report (0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem). Although the PedsQL™ was designed for self-administration for children aged 8-18 and their parents, given the lower socioeconomic and educational level of the participants in the current study, the PedsQL™ was interviewer-administered for both the children and their parents.

Items are reverse-scored and linearly transformed to a 0-100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 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 (this accounts for missing data). If more than 50% of the items in the scale are missing, the scale score is not computed. This accounts for the differences in sample sizes for scales reported in the tables. Although there are other strategies for imputing missing values, this computation is consistent with the previous PedsQL™ peer-reviewed publications, as well as other well-established HRQOL measures. The physical health summary score (eight items) is the same as the physical functioning scale. To create the psychosocial health summary score (15 items), the mean is computed as the sum of the items divided by the number of items answered in the emotional, social, and school functioning scales.

Statistical analyses

Scale internal consistency reliability was determined by calculating Cronbach's coefficient alpha across individual age subgroups.[31] Scales with reliabilities ≥ 0.70 are recommended for comparing patient groups, while a reliability criterion of 0.90 is recommended for analyzing individual patient scale scores.[14,18]

Construct validity was determined utilizing the known-groups method. The known-groups method compares scale scores across groups known to differ in the health construct being investigated. In this study, PedsQL™ 4.0 Generic Core Scales scores in groups differing in known health condition (healthy children and children known to have a chronic illness) were computed,[1,32] using independent sample *t* tests. In order to determine the magnitude of the anticipated differences, effect sizes were calculated.[33] Effect size as used in these analyses was calculated by taking the difference between the healthy sample mean and the chronic sample mean, divided by the healthy sample standard deviation. Effect sizes for differences in means are designated as small (0.20), medium (0.50), and large (0.80) in magnitude.[34]

Construct validity was further tested by correlations with degree of activity of each illness according to physician' criteria on the day of consultation: 0 = no disease activity, 1 = mild disease activity, 2 = moderate disease activity; and 3 = serious disease activity.

Visual analogical scale (VAS) of pain intensity (range of 0-5) and a faces scale (range of 0-6) were used for the measurement of musculoskeletal pain in the last 7 days reported by the patients.

Childhood Health Assessment Questionnaire (CHAQ)[33,35] for evaluation of physical function (range of 0-3) was answered by the parents.

Childhood Health Questionnaire (CHQ)[35,36] for evaluation of the HRQOL (range of 0-100) was answered by the parents. For the purposes of analysis, the CHQ was calculated as psychosocial and physical summary scores. Agreement between child self-report and parent proxy-report was determined through Pearson's correlation coefficients. Statistical analyses were conducted using SPSS version for Windows.[37]

Results

Cognitive interviewing

The translated version of PedsQL™ 4.0 for the Portuguese language/Brazilian culture was administered to a group of patients with rheumatic illnesses followed in our clinic and to their parents or caregivers. Average time of questionnaire administration was 5 minutes for the children and their parents. No significant difficulties with the understanding of the items were noted.

Sample characteristics

The group of patients was constituted of 105 mostly poor children and adolescents (69 girls) aged between 2 and 18 years, with 10 patients between 2 to 4 years, 13 between 5 and 7 years, 41 between 8 and 12 years, and 41 between 13 and 18 years. Rheumatic diseases included juvenile idiopathic arthritis (JIA) (n = 71), systemic lupus erythematosus (n = 22), juvenile dermatomyositis (n = 7) and miscellaneous rheumatic diseases (n = 5). Participants of the healthy group were 240 children and adolescents (124 girls), 60 of each age group (2-4, 5-7, 8-12, 13-18). The PedsQL™ parent proxy-report version was administered to the children's parents or caregiver separately and on the same day.

With relation to the clinical and laboratory disease activity indexes of the patients, according to the ratings of the physicians, 35 patients (33.3%) presented with inactive illness, 37 (35.2%) mild disease activity, 27 (25.7%) moderate disease activity and six (5.7%) serious disease activity. The healthy group was comprised of 240 individuals (124 girls)

Table 1 - Mean scores and standard deviation for the PedsQL™ 4.0 Generic Core Scales for child self-report and parent proxy-report across healthy children and children with rheumatic diseases

		Group						
		Patients			Healthy children			
Scales	Number of items	n	Mean	SD	n	Mean	SD	p
Child-report								
Total score	23	95	74.28	16.73	180	88.90	7.35	< 0.0001
Physical	8	95	75.99	22.65	180	95.94	5.83	< 0.0001
Emotional	5	95	65.89	22.44	180	73.03	16.52	0.0071
Social	5	95	81.63	19.40	180	93.14	10.54	< 0.0001
School	5	91	71.87	18.51	173	89.31	11.80	< 0.0001
Psychosocial summary	15	95	73.33	16.02	180	85.03	9.66	< 0.0001
Parent-report								
Total score	23	105	75.94	15.22	240	92.32	6.01	< 0.0001
Physical	8	105	75.33	22.97	240	97.86	4.31	< 0.0001
Emotional	5	105	68.62	23.18	240	80.52	12.59	< 0.0001
Social	5	105	87.00	16.64	240	96.38	8.89	< 0.0001
School	5	96	72.07	18.57	207	90.93	11.85	< 0.0001
Psychosocial summary	15	105	76.27	14.54	240	89.18	8.19	< 0.0001

SD = standard deviation.

with 60 children or adolescents in each one of the four age ranges.

In the patient group, average age of the parents or caregiver was 38.11±8.84 years and in the healthy control group it was 35.80±9.20 years. In both groups the PedsQL™ was completed primarily by mothers (80%).

Descriptive statistics

The PedsQL™ 4.0 means and standard deviations for child self-report and parent proxy-report for patients and controls are presented in Table 1.

Internal consistency reliability

Table 2 presents the internal consistency of the PedsQL™ summary scores and scales. The Cronbach's alpha for the total scale score was 0.88 for children and parents, indicating excellent internal consistency reliability. The Cronbach's alphas for child and parent reported physical functioning was also excellent, while the Cronbach's alphas for the emotional, social, and school functioning scales were less than the 0.70 standard.

Construct validity

The PedsQL™ scale and summary scores for patient self-report and parent proxy-report of children with rheumatic diseases were significantly lower than the healthy controls, supporting discriminant validity (Table 1).

Table 3 contains the correlations between the PedsQL™ and the pain VAS and pain faces scale, as well as the correlations between the CHAQ and the CHQ. The statistically significant correlations between the PedsQL™ and these previously translated measures further support the construct validity of

Table 2 - Internal consistency (Cronbach's alpha) of the Pediatric Quality of Life Inventory™ 4.0 for children and parents

	Cronbach's alpha			
Aspect	**Children***	**n**	**Parents**	**n**
Total scale score	0.88	264	0.88	264
Psychosocial	0.79	264	0.80	264
Physical	0.85	275	0.87	344
Emotional	0.62	275	0.65	345
Social	0.66	275	0.70	345
School	0.60	264	0.62	264

* PedsQL™ of children aged 5 to 18.
Sample includes healthy children and children with rheumatic diseases.

the PedsQL™ 4.0 Generic Core Scales Brazilian Portuguese version.

Parent/child correlations

To evaluate correlations between child self-report and parent proxy-report, the rheumatic and healthy groups were combined for ages between 5 and 18 years (n = 275 pairs) (Table 4).

Significant correlations were demonstrated between child and parents, with the highest correlation for the physical functioning dimension.

Discussion

This study supports the initial feasibility, reliability and validity of the PedsQL™ 4.0 Generic Core Scales Brazilian Portuguese version for interviewer administration in a sample of mostly poor children with rheumatic diseases in São Paulo. The terminology of the translations was understandable for the patients and controls in São Paulo, as well as for their parents. However, different from the original studies of Varni et al.,[10,11] in which PedsQL™ 4.0 was self-administered in children between 8 and 18 years and parents/caregivers, we opted to read the PedsQL™ (interviewer administration) for all groups. This decision was based on the relatively low schooling levels of many parents and caregivers of the

Table 3 - Correlation with the visual analogue scale and faces scale for pain, Childhood Health Assessment Questionnaire and Childhood Health Questionnaire with the Pediatric Quality of Life Inventory™ 4.0 Generic Core Scales

Scores	**Mean**	**SD**	**Correlation with PedsQL™**	**p**	**n**
VAS variation (0-5)	1.22	1.45	- 0.36	0.0002	103
Faces variation (0-6)	1.21	1.52	- 0.29	0.0030	103
CHAQ variation (0-3)	0.40	0.62	- 0.62	< 0.0001	105
CHQ physical variation (0-100)	43.10	13.17	0.59	< 0.0001	98
CHQ psychosocial variation (0-100)	50.04	8.66	0.65	< 0.0001	98

CHAQ = Childhood Health Assessment Questionnaire; CHQ physical = Childhood Health Questionnaire physical summary score; CHQ psychosocial = Childhood Health Questionnaire psychosocial summary score; Faces = Faces Analogue Scale for Pain; PedsQL™ = Pediatric Quality of Life Inventory™ 4.0; SD = standard deviation; VAS = Visual Analogue Scale for Pain.

Table 4 - Pearson's correlation coefficient for the Pediatric Quality of Life Inventory™ 4.0 Generic Core Scales between child self-report* and parent proxy-report

	Correlation between PedsQL™ for parents and children/adolescents		
Aspect	**r**	**n**	**p**
Physical	0.77	275	< 0.001
Emotional	0.49	275	< 0.001
Social	0.59	275	< 0.001
School	0.73	264	< 0.001
Psychosocial	0.67	275	< 0.001
Total	0.77	275	< 0.001

PedsQL™ = Pediatric Quality of Life Inventory™ 4.0.
* PedsQL™ 4.0 child self-report for children aged 5 to 18.

patients registered at our clinic. These patients had low socioeconomic level as is found throughout a majority of the Brazilian population. Terreri et al.[38] had studied the socioeconomic aspects of 100 families of patients with rheumatic fever registered in our unit and observed illiteracy in 17.3% of parents and 15% of mothers, supporting our observations for the present study regarding reading difficulties.

Patients with rheumatic diseases were selected for this initial validation of the PedsQL™ 4.0 Generic Core Scales Brazilian Portuguese version, since these pediatric diseases have been previously observed to diminish patients' quality of life, with prominence for a significant reduction of physical capacity.[33,35] We observed lower scores for the patients with rheumatic diseases, when compared to the healthy controls, not only in physical functioning, but also in the emotional, social and school/educational functioning dimensions ($p < 0.0001$). Sawyer et al.[19] had evaluated the quality of life of patients with JIA between 8 and 18 years with the PedsQL™ 4.0 Generic Core Scales in Australia, and also observed similar impairment in these four dimensions.

The PedsQL™ 4.0 Generic Core Scales Brazilian Portuguese version correlated with the previously translated Brazilian Portuguese versions of the CHAQ and CHQ ($p < 0.005$ in all correlations),[33,35] further supporting the construct validity of this translation.

For the PedsQL™ 4.0 Generic Core Scales Brazilian Portuguese version, we observed parent/ child intercorrelations of 0.77 for the physical functioning and 0.73 for school functioning, with lower correlations of 0.49 for the emotional functioning and 0.59 for the social functioning. Similar correlations had been observed in the original American- English and international versions.[10,11,14,20-22] These correlations support the importance of including both child self-report and parent proxy-report, since they each represent potentially important but different perspectives on the child's HRQOL.

Similar to the original American-English version,[10] we found the administration of the PedsQL™ to be fast and easy, with an average duration of 3-5 minutes. We observed that the calculation of summary and scales scores was also easy, further adding to the feasibility of the instrument in our country. In a setting such as ours in a public hospital in São Paulo, ease of administration and scoring, without the use of extensive manuals or propriety software, greatly increases the feasibility of use in daily practice and clinical research.

Previously, Varni et al.[18] studied the responsiveness of PedsQL™ 4.0 Generic Core Scales in patients with rheumatic illnesses. We are conducting a similar study to evaluate PedsQL™ 4.0 responsiveness in patients with JIA followed in our service and who receive pharmaceutical interventions and rehabilitation services.

These findings with the PedsQL™ 4.0 Generic Core Scales Brazilian Portuguese version are consistent with previous PedsQL™ translations into German,[20] British English[21] and Norwegian[22] versions. Our data has shown that the internal consistency of PedsQL™ 4.0 was considered adequate in this sample of mostly poor children and their parents. These findings support the initial feasibility, reliability and validity of the Brazilian Portuguese child self-report and parent proxy-report versions of PedsQL™ Generic Core Scales in poor children with rheumatic diseases in São Paulo. Including both child

self-report and parent proxy-report in international clinical trials ensures that both perspectives are heard in the evaluations of new therapeutic interventions for the pediatric rheumatic diseases.

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