

Construct and Criterion Validity of the PedsQL™ 4.0 Instrument (Pediatric Quality of Life Inventory) in Colombia

Abstract

Background: This study aimed at determining the validity of the Pediatric Quality of Life Inventory 4.0 (PedsQL™ 4.0) for the measurement of health-related quality of life (HRQOL) in Colombian children. **Methods:** Validation study of measurement instruments. The PedsQL™ 4.0 was applied by convenience sampling to 375 pairs of children and adolescents between the ages of 5 and 17 and to their parents-caregivers, as well as to 125 parents-caregivers of children between the ages of 2 and 4 in five cities of Colombia (Bogota, Medellin, Cali, Barranquilla and Bucaramanga). Construct validity was assessed through the use of exploratory and confirmatory factor analysis, and criterion validity was assessed by correlations between the PedsQL™ 4.0 and the KIDSCREEN-27. **Results:** The instrument was applied to 375 children (ages 5–18) and 125 parents of children between the ages of 2 and 4. Factor analysis revealed four factors considered suitable for the sample in both the child and parent reports, whereas Bartlett's test of sphericity showed inter-correlation between variables. Scale and subscales showed proper indicators of internal consistency. It is recommended not to include or review some of the items in the Colombian version of the scale. **Conclusions:** The Spanish version for Colombia of the PedsQL™ 4.0 displays suitable indicators of criterion and construct validity, therefore becoming a valuable tool for measuring HRQOL in children in our country. Some modifications are recommended for the Colombian version of the scale.

Keywords: Child, outcome assessment (health care), PedsQL™4.0, psychiatric status rating scales, quality of life, validation studies

Introduction

In recent years, there has been a remarkable increase in research into quality of life as a health indicator in medical specialties, thus becoming an important variable to be considered in cost-utility analysis of interventions in chronic diseases.

Different definitions and ways of rating quality of life have been proposed from a health perspective. In this sense, quality of life has been defined as the value placed upon duration and conditions of life to the extent that it is modified and weakened by injury, illness, treatment, functional states, perceptions, and social opportunities.^[1]

This new perception is known as health-related quality of life (HRQOL) which refers to a state of health, in accordance with the definition issued by the World Health Organization, and the influence of variations in each dimension of an individual's perspective and life expectancy.^[2]

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In the hallmark of research carried out to address HRQOL, general and specific instruments have been developed to assess the perception of patients and their caregivers about their well-being or deterioration as a result of their health-disease process. This is true for the PedsQL™ 4.0 scale, an instrument that has shown adequate markers of validity and reliability^[3,4] having been endorsed and validated in many Spanish-speaking countries^[5-7] and translated into numerous languages. Such a translation of the instrument has been employed in our country, yet no study has been carried out to verify its validity.

The transcultural validation of this type of instrument sets the way for improvement in the quality of HRQOL measurement and enables systematization of its observation as well as proper interaction and communication between researchers working on the same problem.^[8] In this sense, this study attempted to determine the criterion and construct validity of

How to cite this article: Amaya-Arias AC, Alzate JP, Eslava-Schmalbach JH. Construct and criterion validity of the pedsQL™ 4.0 instrument (Pediatric Quality of Life Inventory) in Colombia. *Int J Prev Med* 2017;8:57.

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Access this article online

Website:
www.ijpvmjournal.net/www.ijpvm.ir

DOI:
10.4103/ijpvm.IJPVM_194_16

Quick Response Code:



the PedsQL™ 4.0 for measuring HRQOL in Colombian children.

Methods

Population

The inclusion criteria for the present study were: Colombian children and adolescents aged 2–18 years and their parents-caregivers, who received outpatient care or hospitalization at a secondary or tertiary health facility in the cities of Bogota, Barranquilla, Cali, Medellin and Bucaramanga, and who voluntarily participated in the study.

The only exclusion criterion was incapacity for completing the instruments due to illiteracy, cognitive impairment, or sensory disturbances.

Health care facilities where the PedsQL™ 4.0 was administered were selected by convenience sampling in the five cities stated above, and selection criteria were secondary/tertiary level of care and voluntary participation in the study.

Design

Observational validation of measurement instruments consisting of the following phases:

Phase 1: Construct validity

Construct validity was evaluated using exploratory factor analysis. As a strategy for extracting factors the following criteria were used: Eigen value >1, Barlett test and Kaiser–Meyer–Olkin test, comparing with the main component extraction process to determine the scale domains. A Varimax orthogonal rotation was performed to improve the interpretability of the factors after assessing the low correlation between items. Furthermore, a confirmatory factor analysis was undertaken with the calculation of the following fit indexes: Comparative fit index, normed fit index, root mean square error of approximation (RMSEA), goodness of fit index.

In this phase, a convenience sampling was performed: the sample size was determined to be 5 subjects per item, and accounting for possible missing data, for a total of 125 subjects.^[9] Considering the fact that the instrument has some variations when applied in four age groups and that it is administered to the minor and his/her caregiver, for those groups aged 5 years or older the equivalent of this sample size was collected for each group as follows: One hundred and twenty-five caregivers of children aged 2–4 years; 125 children aged 5–7 years and their parents-caregivers; 125 children aged 8–12 years and their parents-caregivers and 125 children aged 13–17 years and their caregivers.

Phase 2: Criterion validity

To assess criterion validity (concurrent validity) the KIDSCREEN-27 scale was applied simultaneously to

children aged 8–17 years. This scale was selected due to its validation in our country and the fact that it is designed to measure HRQOL in children aged 8–18 years. The study performed in our country found that KIDSCREEN-27 has good psychometric standards. The Spearman correlation coefficient between the two subscales was calculated taking into account they are ordinal variables.^[10]

A sample size of 46 was calculated to detect a correlation of 0.4, with a significance level of 0.05 and 80% power. Given the fact that the relative efficiency of Spearman's rank correlation compared to Pearson's correlation was 0.91,^[11] a correction was made to adjust the power when calculating Spearman's coefficient, that means 50 children were required (for two age groups) for a total of 100 (50 children aged 8–12 years and 50 children aged 13–17 years).

This sample was taken strictly in a sequential fashion under the order of application, in each of the above-mentioned groups, until completion of the required sample size.

Instruments

The Pediatric Quality of Life Inventory™ (PedsQL™ 4.0) was originally developed in the English language by Varni *et al.*^[3,4] The generic module evaluates four dimensions: Physical functioning (8 items), emotional functioning (5 items), social functioning (5 items), and school functioning (5 items), for a total of 23 items using a five-point Likert scale. Higher scores indicate better HRQOL and, in addition to the subscales, it is possible to create a Psychosocial Health Summary Score (resulting from the mean of the emotional, social, and school functioning subscales).

The scale has four versions according to the child's age as follows: 2–4 years (toddlers), 5–7 years (young children), 8–12 years (children) and 13–18 years (teenagers). Furthermore, there is an additional format to be administered to parents or caregivers of children aged 5–18 years known as the parent-proxy report. Administration of the PedsQL™ 4.0 takes 10–15 min and its psychometric properties have been verified in different languages and contexts, with good standards of reliability and validity.^[6,12-16]

KIDSCREEN-27 includes 27 items (using a 5-point Likert-scale) that measure 5 HRQOL dimensions: Physical well-being (5 items); psychological well-being (7 items); autonomy and parent relations (7 items); social support and peers (4 items); school environment (4 items). As to the exploratory factor analysis, validation performed in Colombia showed six categories validated also in the confirmatory factor analysis. Internal consistency was above 0.7 in all dimensions. In all domains the intraclass correlation coefficient was higher than 0.87 pertaining interobserver reliability and >0.8 as to intraobserver reliability.^[10]

Control bias

The administration procedure of the scale was standardized through practitioner training and heterogeneous sampling in five different cities granted it included children with different health problems which consulted for outpatient services or hospitalization.

Results

The PedsQL™ 4.0 was administered to 375 children aged 5–18 years and their parents, as well as to 125 parents of children aged 2–4 years. The sample included pairs for each age group (50% of boys and 50% of girls). Each age group corresponded to 25% of the sample and 20% of the sample was measured in each city, fulfilling the standards purported for the sample contrived.

Two hundred and forty-five children presented acute illnesses (49%) and 255 presented chronic illnesses (51%). The most common diagnoses by percentages were: Oncologic and hematologic diseases (12%), asthma (8%), dengue fever (7%), other chronic diseases (19%), and other acute diseases (21%). Nearly 34% of the children had some physical limitation, and 22% was not enrolled in school

activities at the time of evaluation due to their health problem.

Phase 1: Construct validity

Exploratory factor analysis

The exploratory factor analysis for the child report was conducted to obtain four factors that explained for 100% of the variance and showed an Eigen value ≥ 1 ; assessment of the sample's adequacy using the Kaiser–Meyer–Olkin test indicated that the variables measured common factors when obtaining an index of 0.847, and Bartlett's test of sphericity showed a significance level of <0.0001 with Chi-square distribution of 4414.3 and 253 degrees of freedom, suggesting that variables are inter-correlated. Table 1 depicts the rotated matrix for the child report.

Table 1 shows the physical and school functioning subscales with proper markers of internal consistency (alphas = 0.821 and 0.969, respectively), both clustered as originally purported. The emotional functioning subscale only includes three of its items in one domain, the emotional item 5 is not grouped in any domain, and emotional item 4 is grouped with the items of the physical functioning subscale. As for

Table 1: Factor loadings corresponding to Varimax orthogonal rotation with four factors from the Pediatric Quality of Life Inventory 4.0 child report

Item	Factor 1	Factor 2	Factor 3	Factor 4	Uniqueness
Total alpha 0.842 (0.842-0.823)					
Physical functioning, alpha 0.821 (IC: 0.821-0.797)					
Physical 1: To walk		0.6702			0.5056
Physical 2: To run		0.7974			0.3563
Physical 3: To do sports activity/exercise		0.7894			0.3617
Physical 4: To lift something heavy		0.5567			0.6268
Physical 5: To take a shower by myself		0.4677			0.7535
Physical 6: To do chores around the house		0.4984			0.7338
Physical 7: Hurt or ache		0.4354	0.4220		0.6257
Physical 8: Low energy		0.4106	0.3809		0.6690
Emotional functioning, alpha 0.598 (IC: 0.598-0.541)					
Emotional 1: Afraid or scared			0.6018		0.6163
Emotional 2: Sad or blue			0.6135		0.6002
Emotional 3: Angry			0.3838		0.7525
Emotional 4: Trouble sleeping		0.3425			0.7911
Emotional 5: Worry about what will happen to me					0.8515
Social functioning, alpha 0.529 (IC: 0.528-0.462)					
Social 1: Trouble getting along with other kids				0.5323	0.6963
Social 2: Other kids do not want to be my friend				0.6805	0.5353
Social 3: Other kids tease me				0.5502	0.6810
Social 4: Cannot do things that other kids my age can do		0.3904	0.3160		0.6853
Social 5: It is hard to keep up when I play with other kids		0.4049			0.7180
School functioning, alpha 0.969 (IC: 0.969-0.964)					
School 1: To pay attention in class	0.9387				0.1160
School 2: Forget things	0.9208				0.1464
School 3: Trouble keeping up with my schoolwork	0.9491				0.0987
School 4: Miss school because of not feeling well	0.9085				0.1702
School 5: Miss school to go to the doctor or hospital	0.9223				0.1396

the social functioning subscale, three of its items are grouped in a common domain, and the other two are grouped in the physical functioning subscale (social 4 and 5).

When reviewed in terms of wording, items of the emotional and social subscales that were clustered in the physical functioning subscale might be interpreted as if evaluating physical aspects related to mobility (I have trouble sleeping, I do things that others can do, and I keep up when I play with others). On the other hand, children might have difficulty understanding item 5 of the emotional subscale (which is not clustered), since they may portray poor insight on future expectations.

The exploratory factor analysis for the parent report was conducted to obtain four factors that explained for 96% of the variance and showed an Eigen value ≥ 0.8 ; assessment of the sample's adequacy using the Kaiser–Meyer–Olkin test indicated that the variables measured common factors when obtaining an index of 0.844; Bartlett's test of sphericity showed a significance level of <0.0001 with Chi-square distribution of 2892.7 and 253 degrees of freedom, suggesting that variables are inter-correlated. Table 2 depicts the rotated matrix for the parent report.

The results for the physical and social functioning subscales are similar for the parent report, whereas the emotional functioning subscale grouped four of its items and left item 5 unclustered, as was the case for the child report. Unlike the child report, items were not clustered in one domain; two of its items were grouped into the physical functioning subscale (school 4 and 5), given the fact that both items could potentially assess physical functioning aspects in the child report.

Confirmatory factor analysis

The child report's confirmatory factor analysis replicated the four-factor model purported in the exploratory factor analysis. Table 3 depicts a proper fit on the RMSEA as well as the factor loadings for each item, both for the 4 multidimensional scale and the generic core scale which explains the quality of life construct.

Figure 1 depicts the resulting scale based on exploratory factor analysis. The results of the scale's fit indices are presented in Table 3.

The four-factor model was also tested in the parent report as purported in the exploratory factor analysis. In this version proper fit was not found in any of the indices

Table 2: Factor loadings corresponding to Varimax orthogonal rotation with four factors from the Pediatric Quality of Life Inventory 4.0 parent-proxy report

Item	Factor 1	Factor 2	Factor 3	Factor 4	Uniqueness
Total alpha 0.868 (0.868-0.850)					
Physical functioning, alpha 0.821 (IC: 0.821-0.797)					
Physical 1: To walk	0.6859				0.5187
Physical 2: To run	0.8694				0.2346
Physical 3: To do sports	0.8392				0.2697
Physical 4: To lift something heavy	0.6454	0.3469			0.4526
Physical 5: To take a shower by myself	0.5261				0.6744
Physical 6: To do chores around the house	0.4863				0.7175
Physical 7: Hurt or ache	0.3455	0.4320			0.6886
Physical 8: Low energy	0.3708	0.5133			0.5935
Emotional functioning, alpha 0.598 (IC: 0.598-0.541)					
Emotional 1: Afraid or scared		0.6845			0.4769
Emotional 2: Sad or blue		0.7617			0.3627
Emotional 3: Angry		0.3543	0.3131		0.7140
Emotional 4: Trouble sleeping	0.3802	0.3285			0.7284
Emotional 5: Worry about what will happen to me					0.8450
Social functioning, alpha 0.529 (IC: 0.528-0.462)					
Social 1: Trouble getting along with other kids			0.5409		0.6209
Social 2: Other kids do not want to be my friend			0.7215		0.4438
Social 3: Other kids tease me			0.6334		0.5766
Social 4: Cannot do things that other kids my age can do	0.5101	0.3999			0.5544
Social 5: It is hard to keep up when I play with other kids	0.4950				0.6255
School functioning, alpha 0.969 (IC: 0.969-0.964)					
School 1: To pay attention in class				0.5863	0.6153
School 2: Forget things				0.5977	0.6028
School 3: Trouble keeping up with my schoolwork				0.6382	0.5244
School 4: Miss school because of not feeling well	0.3427				0.7394
School 5: Miss school to go to the doctor or hospital	0.3727				0.6880

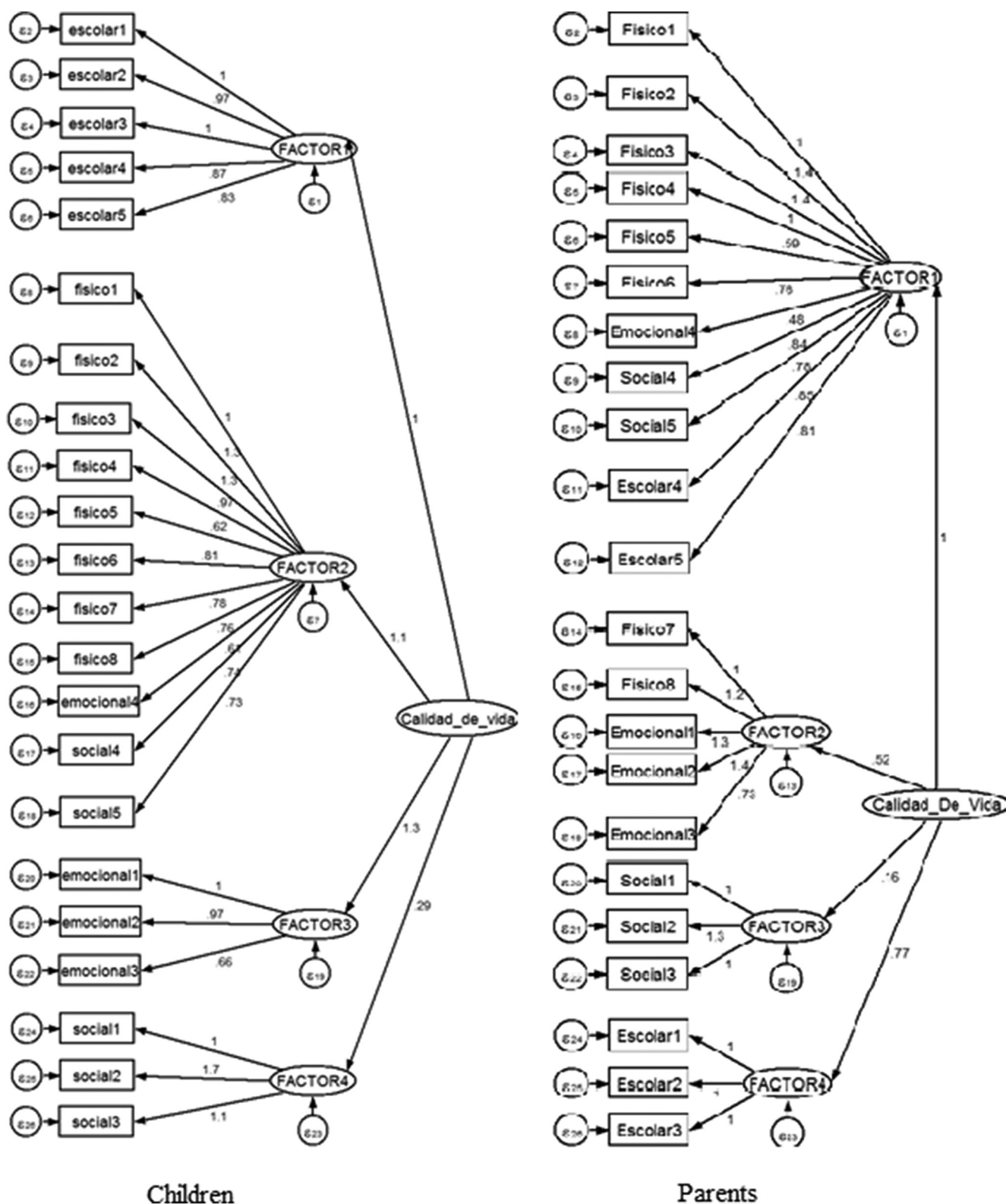


Figure 1: Confirmatory factor analysis (children and parents); four multidimensional scale-based model for the “quality of life” construct

[Table 3 and Figure 1]. Unlike the child report, items for the physical subscale were not grouped in one factor and items 1, 2, and 3 for the social subscale were clustered accounting for a domain in the core scale for both models.

Phase 2: Criterion validity

Table 4 depicts the results of the Spearman’s correlation coefficient between the PedsQL™ 4.0 and the

Table 3: Model fit indices (child and parent-proxy report)

Child report		Parent-proxy report	
Fit index	Result	Fit index	Result
GFI	681.3 ($P<0.0001$)	GFI	1908.76 ($P<0.0001$)
CFI	0.89	CFI	0.679
NFI	0.87	NFI	0.637
RMSEA	0.08	RMSEA	0.149

GFT=Goodness of fit index, CFI=Comparative fit index, NFI=Normed fit index, RMSEA=Root mean square error of approximation

Table 4: Spearman correlation coefficient between the Pediatric Quality of Life Inventory 4.0 and the KIDSCREEN-27 scales

PedsQL 4.0	KIDSCREEN-27	Observations	Spearman's rho	P
Total	Total	122	0.4746	0.0000
Physical	Physical well-being	122	0.4407	0.0000
Emotional	Psychological well-being	122	0.4788	0.0000
Social	Autonomy and parents	122	0.1184	0.1938
Social	Peers and social support	122	0.2480	0.0059
School	School environment	122	0.3407	0.0007

PedsQL 4.0=Pediatric Quality of Life Inventory 4.0

KIDSCREEN-27 for determining the scale's criterion validity.

The results demonstrate there is an intermediate relationship between the physical functioning and the physical well-being subscales, as well as the emotional functioning and psychological well-being subscales. Total scores also displayed an intermediate correlation.

The social functioning subscale was not related to either the autonomy and parent relations or the social support and peers subscales.

Discussion

The size and characteristics of the sample in this study enhances its heterogeneity and the representativeness of the results, especially when considering the fact that unlike other validations of this scale in which healthy children were included^[6] or the sample sizes were smaller,^[5,7] this study included children with acute and chronic diseases in five Colombian cities.

Reliability results were acceptable for both the parent-proxy and child report in the generic core and dimension subscales, this is consistent with the original version of the scale and the Argentinian and Spanish validations.^[5,6]

During the scale's validation process, specifically for construct validity, it was found that in both reports the "quality of life" construct was explained by four dimensions in both the exploratory and confirmatory factor

analysis, along with measures of sampling adequacy. However, the scales did not show the acceptable goodness of fit. This could be because some items (emotional 3, 4, 5, for both scales; school 4 and 5 for parents and social 5 for children) presented a high uniqueness factor. For this reason, it should be considered not to include them in the Colombian version, modify their wording or reformulate the way in which the emotional, school, and social subscales are constructed. These findings are similar to those made in the Spanish validation,^[5] specifically in the school functioning and physical well-being dimensions. In the case of the "health care satisfaction" module belonging to the Uruguayan validation, applicability problems were encountered.^[7]

Regarding criterion validity, the results revealed a positive linear relationship between the PedsQL™ 4.0 and the KIDSCREEN-27 scales for both the total scores and subscale scores, except in the case of the social factor subscale, in which Spearman's rank correlation coefficient was not statistically different from 0. These results might be related to how each subscale measured these domains as they focus on different aspects. For example, the social functioning subscale of PedsQL™ 4.0 focuses on how hard it is for the child to interact with his/her peers, while the KIDSCREEN-27 focuses on the social support the child receives from his/her family or peers.

For further studies, it is expected that an assessment is performed in children with chronic disease in terms of their quality of life, taking into account the transition between subscales to verify if the changes are due to the subscale or the medical condition itself. Moreover, other items could be potentially included, such as the use of available technological advances (mobile devices, virtual games, physical activities, etc.) that may prove useful to enhance the perception of quality of life by children with chronic illness and their parents.

At present, it is recognized that the measurement of quality of life in children is of the utmost importance and is a factor to be considered in clinical decision making. Therefore, it is necessary to make available different instruments in Colombia validated for assessing children with different pathologies.

Conclusions

In conclusion, the validation process for the PedsQL4.0™ scale for Colombia displayed acceptable validity, revealing a different structure from the authors' original proposal, especially with regards to the social, emotional, and school aspects of the instrument.

Acknowledgments

We thank all institutional health service providers that allowed us access to their facilities for data collection:

Fundación Hospital de la Misericordia (Bogotá, D.C), Hospital Universidad del Norte (Barranquilla), Fundación Club Noel (Cali), Clínica Universitaria Bolivariana (Medellín) y el Hospital Universitario de Santander (Bucaramanga).

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Received: 30 May 16 **Accepted:** 29 Mar 17

Published: 24 Aug 17

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