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Development and validation of the Child Oral Health Impact Profile – Preschool version

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Objective: The Child Oral Health Impact Profile (COHIP) is a validated instrument created to measure the oral health-related quality of life of school-aged children. The purpose of this study was to develop and validate a preschool version of the COHIP (COHIP-PS) for children aged 2-5. ***Basic research design***: The COHIP-PS was developed and validated using a multi-stage process consisting of item selection, face validity testing, item impact testing, reliability and validity testing, and factor analysis. ***Participants***: A cross-sectional convenience sample of caregivers having children 2-5 years old from four groups completed item clarity and impact forms. Groups were recruited from pediatric health clinics or preschools/daycare centers, speech clinics, dental clinics, or cleft/craniofacial centers. Participants had a variety of oral health-related conditions, including caries, congenital orofacial anomalies, and speech/language deficiencies such as articulation and language disorders. ***Main outcome measure***: COHIP-PS. ***Results***: The COHIP-PS was found to have acceptable internal validity (a = 0.71) and high test-retest reliability (0.87), though internal validity was below the accepted threshold for the community sample. While discriminant validity results indicated significant differences across study groups, the overall magnitude of differences was modest. Results from confirmatory factor analyses support the use of a four-factor model consisting of 11 items across oral health, functional well-being, social-emotional well-being, and self-image domains. ***Conclusions***: Quality of life is an integral factor in understanding and assessing children's well-being. The COHIP-PS is a validated oral health-related quality of life measure for preschool children with cleft or other oral conditions.

Keywords: *cleft palate; cleft lip; child, preschool; quality of life; oral health; psychometric*

Introduction

Quality of life (QoL), or individuals' "perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns"(WHOQOL, 1995), is considered a valid parameter in patient assessment for all populations, including preschool children (Sischo and Broder, 2011). These subjective perceptions of treatment need or outcomes offer a valuable addition to clinical evaluations. In measuring QoL, however, it is imperative to consider the developmental processes of the targeted age group. For preschool children who are seeking independence, have increased social interactions, and are developing both expressive and receptive communication skills, psychosocial development is a key component of both their QoL and oral health-related quality of life (OHRQoL). OHRQoL, defined as the impact of oral conditions or diseases on quality of life, is a multidimensional construct that includes oral symptoms, functional (e.g., speech, dental) and psychosocial well-being, and other factors relevant to preschool children (Broder et al., 2014a; Reisine and Locker, 1988). Given the importance of children's oral health in overall health and QOL (Mouradian, 2001), assessing OHRQoL is vital to understand patient well-being and determine treatment efficacy.

The Child Oral Health Impact Profile (COHIP) is a validated instrument used to assess OHRQoL in school-aged children (Broder et al., 2007). Unlike many OHRQoL measures, the COHIP includes both positive and negative perceptions of health and health outcomes. It has good psychometric properties (Broder and Wilson-Genderson, 2007), has been translated into numerous languages and is available in a short-form version (Broder et al., 2012a). COHIP has been successfully used in research on school-aged youth with cleft lip and/or palate (cleft refers to failure of fusion in the orofacial complex, including cleft lip with or without cleft palate, isolated cleft palate, and facial clefts (Mooney et al., 2016) and their caregivers (i.e., parents or adults responsible for the care of the child), as well as dental conditions to describe impacts related to OHRQoL (Ahn et al., 2012; Asgari et al., 2013; Broder et al., 2012b; Broder et al., 2014b; Broder et al., 2017; Geels et al., 2008; McGrath and Broder, 2014; Ravaghi et al., 2011; Ruff et al., 2016).

Like the COHIP, many child OHRQoL measures, with the exception of the Early Childhood Oral Health Impact Scale (ECOHIS) (Pahel et al., 2007), are validated for school-aged rather than preschool-aged children (Genderson et al., 2013). While the ECOHIS has been used to examine the impact of early childhood caries on OHRQoL (Arrow and Klobas, 2015; Lee et al., 2010), it has not been applied to other developmental issues salient in the preschool years,

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including speech problems and/or conditions like craniofacial anomalies. Therefore, health services research would benefit from an OHRQoL instrument validated for preschool children that could be used across oral health and related conditions that potentially impact preschool children's' well-being.

The objective of this study was to develop and validate the Child Oral Health Impact Profile-Preschool version (COHIP-PS). Using a multi-staged approach, we sought to create a valid and reliable instrument that could distinguish between children with different clinical conditions (e.g., dental conditions, speech differences) and children representing a community sample of healthy children. Our goal was to develop a comprehensive, self-administered questionnaire that could be completed by caregivers (CG) for both clinical practice and research to assess OHRQoL in preschool-aged children.

Methods

Initial items considered for the COHIP-PS were first drawn from the original COHIP instrument across five theoretical domains: oral symptoms, functional well-being, social-emotional well-being, self-image, and school activities. Items considered developmentally relevant to preschool children were included; items not considered physically, emotionally, or socially relevant to preschool-aged children were discarded. Included items were re-worded to apply to the specific age group (e.g., the original COHIP item "Missed school for any reason" was changed to "Missed preschool or daycare for any reason"). Similar to the original COHIP, pronouns were used to indicate that caregivers were completing the COHIP-PS on behalf of their children. In addition to original COHIP items, new items were developed based on qualitative data from a prior study of caregivers of children with cleft (Sischo et al., 2015); and items adapted from established questionnaires (e.g., the Child Health Questionnaire) for the targeted age group were also included. This process resulted in 26 proposed items related to OHRQoL and two global health items that rated the child's oral and general health. Once the initial item pool was generated, seven sites in the United States were chosen to collect face validity and/or item impact data. Items from this pool were then evaluated for validity and reliability, and poor items were removed from the final instrument. Items were reversed scored such that higher COHIP-PS scores indicate better OHRQoL. Initial items are presented in Supplementary Appendix 1.

A standard, multi-staged process was used to develop and validate the COHIP-PS (Guyatt et al., 1993; Juniper et al., 1992), which included development of the initial item pool, face validity testing, item impact testing and item response characteristics, reliability and validity testing, and factor analysis. Face validity data were collected at three sites (Atlanta, Philadelphia, and New York); while item impact data were collected at seven sites (Chicago, Chapel Hill, Atlanta, Columbus, Pittsburgh, Philadelphia, and New York). Human subjects approval from an Institutional Review Board (IRB) was secured at all study sites.

Participants

Participants in each data collection phase included a cross-sectional convenience sample of male and female caregivers (i.e., the individual providing primary care for the child, usually the parent) of children 2-5 years of age. Caregiver participants were drawn from four groups: those seeking evaluation or care for children with cleft lip and/or palate (cleft sample), those seeking speech therapy for children (speech sample), those seeking routine pediatric dental care for children (dental sample), or children from surrounding communities (community sample). The caregiver is considered the most reasonable proxy for reporting QoL in young children (Marshman and Robinson, 2007; Marshman and Hall, 2008). Children were excluded if they had any other major medical issues or syndromes. Caregivers were required to read English or Spanish.

Procedures

During both the face validity and item impact testing phase, research staff approached eligible individuals to request participation in the project. Caregivers of children with cleft were recruited during clinic appointments by research staff who had previously verified study eligibility via electronic health records. Caregivers of children in the dental and speech samples were approached in the waiting room before or after their appointments by research staff. For the community sample, caregivers of eligible children were identified either by daycare, pediatric clinic, or listserv staff. During recruitment, the research staff explained the purpose of the study along with eligibility and participation requirements. If willing to participate, caregivers provided verbal consent as per IRB regulations at each site. Participants received a toothbrush and toothpaste for participation in face validity testing and a modest monetary incentive for participating in item impact testing. All instrument forms were translated into Spanish. Data collection occurred between July 2015 and September 2016.

Data Analysis

Item impact testing was used to measure the frequency and relevance of each of the initial 26 items across groups. For each item, we computed endorsement, relevance, and impact scores. Endorsement was computed as the proportion of participants with frequency ratings from 'all the time' to 'sometimes'. Relevance was computed as the average relevance rating for each item, ranging from 0 ('not at all') to 3 ('very much'). Impact was computed as the product of frequency and relevance scores for each item. Items that had extremely high or low endorsement, low impact, or were highly correlated and therefore possibly redundant were removed (Juniper *et al*, 1992).

Item response characteristics were evaluated using a one-parameter Rasch model. Each item was dichotomized into a positive or negative OHRQoL response and summed to a total score. Item responses of "All the time" or "Often" were classified as negative OHRQoL and "Sometimes" or "Never" as positive OHRQoL. Individual items were reverse scored where appropriate. This total score was then treated as a latent variable and used as a predictor for each binary item in a logistic regression model. Finally, a multilevel mixed effects logistic regression model was fit with coefficients for each question and evaluated for statistical significance.

Item-level analyses consisted of reliability and validity testing. Missing data were evaluated by identifying the number of items in which >5% of the sample had a missing response. For scale-level analyses, floor and ceiling effects were reviewed using box plots and univariate statistics.

Internal consistency was determined using Cronbach's alpha. For the overall scale, the acceptable level was set at 0.70. Items were evaluated for consistency based on the alpha for the overall scale and within each sample (dental, speech, cleft, and community). Test-retest reliability was determined using the intraclass correlation coefficient and canonical correlation. A random sample of individuals was either given or mailed a retest questionnaire to be completed approximately two weeks after the initial testing took place. Acceptable test-retest reliability was set at 0.70.

Discriminant and convergent validity were used to assess construct validity. Discriminant validity, or the ability of the COHIP-PS to differentiate among groups, was assessed by comparing COHIP-PS scores across the four groups using analysis of covariance, controlling for demographic characteristics. As the type and severity of oral health status of these groups was expected to differ, discrimination was hypothesized as significant differences in COHIP-PS. Construct validity was also assessed by examining the association between cleft type, clinical severity for dental participants as measured by the number of decayed, filled, or missing teeth (dmft), and COHIP-PS scores using partial Spearman correlations, controlling for gender and ethnicity. It was expected that cleft type (cleft lip and palate compared to cleft lip only or cleft palate only) and a higher dmft would be associated with lower COHIP-PS scores.

Convergent validity was evaluated by examining the partial Spearman correlation between COHIP-PS scores and a proxy-reported global oral health measure, adjusting for gender and ethnicity. A significant positive correlation between the COHIP-PS and global oral health scores would indicate that better OHRQoL is associated with better global health.

To test the factor structure of the COHIP-PS, a confirmatory factor analysis (CFA) was conducted to determine whether the established COHIP domains were appropriate to measure oral health-related quality of life in preschool-aged children. Overall Goodness of Fit was assessed using the Root Mean Square Error of Approximation (RMSEA), the Comparative Fit Index (CFI), and the Tucker-Lewis Index (TLI). Acceptable RMSEA was set at a maximum of 0.70, while CFI and TLI criteria were set at a minimum of 0.90. Analyses were conducted using Stata v14.2. Statistical significance was set at 0.05.

Results

A total of 327 caregivers were included in the sample: 81 in the cleft group, 69 in the speech group, 75 in the community group, and 102 in the dental group (Table 1). Approximately 84% of the caregivers were female, while 48% of children were female. For children, 43% were white, followed by 33% Latino, 11% Black, 7% Pacific Islander, 4.7% other, and 1.5% Indian. For the cleft sample, 45 participants had cleft lip and palate (62%), 21 had cleft palate only (29%), and 7 had cleft lip only (9%).

Face validity

To ensure clarity of items and ascertain whether items should be omitted, reworded, or added as perceived by the participants, a form was created for participants to rate the clarity of each item. Eight healthcare professionals finalized the form, which was then completed by 204 caregivers (48 cleft, 41 speech, 58 dental, and 57 community). Participants had the opportunity to provide qualitative feedback and offer suggestions on missing, irrelevant, and/or confusing items.

Table 1. Demographic characteristics of the three clinical groups and the community group

	Overall *n = 327*	*Cleft* *n = 81*	*Speech* *n=69*	*Community* *n=75*	*Dental* *n=102*
	%	*%*	*%*	*%*	*%*
Child gender					
Male	54.23	58.23	58.82	47.22	53.00
Caregiver gender					
Male	16.29	18.99	13.43	16.90	15.63
Female	83.71	81.01	86.57	83.1	84.38
Race/ethnicity					
Asian/Pacific Islander	7.21	17.28	3.13	4.11	3.96
Indian	1.57	1.23	0	2.74	1.98
Latino	32.92	20.99	17.19	15.07	65.35
Black	10.97	8.64	20.31	1.37	13.86
White	42.63	46.91	54.69	73.97	8.91
Other	4.70	4.94	4.69	2.74	5.94
Data collection site					
NYU	57.49	17.28	33.33	65.33	100
NCH	19.27	27.16	57.97	1.33	0
USC	1.53	6.17	0	0	0
PITT	1.22	4.94	0	0	0
UNC	6.42	18.52	0	8	0
CHOA	3.06	8.64	4.35	0	0
CHOP	4.89	0	0	21.33	0
UIC	6.12	17.28	4.35	4.00	0

Based on the item evaluation data, eight items were identified as ‘unclear’. Issues relating to self-image, empathy, and adversity were considered unclear by some caregivers. In the qualitative portion of data collection, some caregivers reported that these items were unclear due to their child’s age, particularly for the younger children. The empathy item was found to be particularly unclear by the caregivers, so was removed from the item pool. Fewer than 10% of caregivers deemed the other items unclear, and thus they were retained. The initial COHIP-PS item pool that was evaluated for validity and reliability is shown in Appendix 1.

Item impact testing and item response characteristics

Impact scores for each COHIP-PS item were calculated by sample and domain (Appendices 1-5). Frequency scores indicate how often an item was experienced over the past three months using a four-point scale ranging from “never” to “all the time”. Relevance was measured by a four-point scale ranging from “not at all” to “very much”. Items were ranked within the theoretical domains (oral symptoms, self-image, functional well-being, social/emotional well-being, and school/daycare) according to their impact scores. Low impact or mean scores were found for items 8, 12, 13, 19, 22, and 24. Additionally, Rasch model results indicated that items 8, 14, 15, 20, and 26 were not statistically significant. Based on these results, all of the identified problematic items were removed with the exception of item 14 (“Been teased, bullied or called names by other children because of his/her teeth, mouth, or face”), which was retained for substantive purposes and subjected to further evaluation.

Reliability and validity testing

For a large majority of items, participants utilized the full range of response choices. Item distribution tended to be skewed toward positive OHRQoL. Missing scores were <5% for all but six COHIP-PS items across all children in the sample. Review of box plots of the overall COHIP-PS by group and by subscale indicated comparable variability across group and scale.

Cronbach’s alpha for the overall COHIP-PS was 0.71, indicating acceptable reliability (Table 2). Following initial estimation of Cronbach’s alpha, items 7, 11, and 14 were removed to improve internal consistency. Internal consistency estimates for the cleft, speech, community, and dental groups were 0.74, 0.71, 0.66, and 0.78, respectively. For test-retest reliability, 102 participants who completed questionnaires approximately two weeks apart were included in the analysis. Only participants whose children did not undergo treatment were included in this phase, as treatment could impact OHRQoL retest scores. Dental participants did not complete retest instruments.

Table 2. Overall COHIP-PS Reliability by group

	Total	*Cleft*	*Speech*	*Community*	*Dental*
Reliability measure					
Cronbach’s alpha	0.71	0.74	0.71	0.66	0.78
Intraclass Correlation Coefficient	0.87	0.92	0.87	0.81	*
Canonical Correlation	0.87	0.95	0.88	0.80	*

*No retest conducted in this group

The test-retest response rate was 90%. Intraclass correlation coefficients (ICCs) indicated excellent consistency of the overall COHIP-PS (0.87). The canonical correlation for the overall COHIP-PS was also high (0.87). Canonical correlations and ICCs were similar across cleft, speech, and community groups.

ANCOVA results indicate mean ratings of COHIP-PS and individual subscale scores across groups differed significantly, after controlling for gender and ethnicity (Table 3). Caregivers of children with cleft had lower overall COHIP scores than those with speech or dental concerns, as well as the community sample. The community sample had the highest COHIP-PS scores. However, mean differences between each sample were small for the overall COHIP-PS and COHIP-PS domain scores. When adjusted for child gender and race/ethnicity, the clinical severity of caries (dmft) correlated with total COHIP-PS ($r_s = -0.36$, $p = 0.03$) and the subscale scores for oral health, functional well-being and social-emotional well-being ($r_s = -0.47$, $p = 0.003$; $r_s = -0.25$, $p = 0.02$; $r_s = -0.31$, $p = 0.003$ respectively) but not with self-image ($r_s = -0.09$, $p = 0.43$) (Table 4). Partial Spearman correlations between the overall COHIP-PS and cleft type was not significant; only the oral health subscale was significantly correlated with cleft type ($r_s = 0.28$, p = .04).

Table 4. Partial Spearman correlations* of clinical severity (dmft) with overall COHIP-PS and subscale scores

	Dental	
	r(s)	*p-value*
COHIP-PS	-0.36	0.03
Oral Health	-0.47	0.003
Functional well-being	-0.25	0.02
Social-Emotional well-being	-0.31	0.003
Self-Image	-0.09	0.43

*Correlation coefficients adjusted for child gender and race/ethnicity

Table 3. Analysis of covariance* results for COHIP-PS by group

	Overall COHIP		*Oral Health*		*Functional well-being*		*Social/emotional*		*Self-Image*	
	Mean	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
Test Group										
Cleft	46.25	4.79	15.6	2.21	12.38	2.32	7.76	0.75	10.31	1.61
Speech	48.31	3.69	18.51	1.85	12.07	1.97	7.90	0.40	9.80	1.72
Community	48.41	3.48	17.99	1.63	13.90	1.68	7.80	0.55	9.09	1.67
Dental	46.44	5.02	16.71	2.11	13.60	1.93	7.41	0.98	10.22	1.93
F-statistic, p-value	5.12	p = .002	22.81	p < .0001	12.82	p < .0001	6.44	p < .001	5.11	p = .002

*Models adjusted for child gender, caregiver gender, and child race/ethnicity

Table 5. Partial Spearman correlations* between global health status, COHIP-PS, and subscale scores by group

	Cleft		*Speech*		*Community*		*Dental*	
	r(s)	*p-value*	*r(s)*	*p-value*	*r(s)*	*p-value*	*r(s)*	*p-value*
Global Oral Health								
COHIP-PS	0.44	0.0007	0.50	0.0005	0.41	0.0006	0.49	0.0023
Oral Health	0.41	0.0014	0.28	0.05	0.38	0.0012	0.49	0.0013
Functional well-being	0.51	< .0001	0.44	0.0014	0.25	0.04	0.48	<.0001
Social-Emotional well-being	-0.01	0.94	0.18	0.21	0.10	0.43	0.42	<.0001
Self-image	0.05	0.70	0.26	0.07	0.20	0.09	0.10	0.33

*Correlation coefficients adjusted for child gender and race/ ethnicity

Partial Spearman correlations (Table 5) between global oral health status and COHIP-PS scales, adjusting for child gender and child race/ethnicity, indicate statistically significant associations across scales and groups. The overall COHIP-PS was significantly associated with global oral health status for the cleft ($r_s = 0.44$, $p < .001$), speech ($r_s = 0.50$, $p < .001$), community ($r_s = 0.41$, $p < .001$), and dental groups ($r_s = 0.49$, $p = .002$). Correlations were of moderate magnitude.

Factor analysis

Confirmatory Factor Analysis of the proposed original five domains from the parent COHIP instrument was found to be of inadequate fit for use in preschool aged children. Re-estimation following structural modifications resulted in a four-factor model consisting of oral health (items 1, 3, and 5), functional well-being (items 9 and 18), social-emotional well-being (items 6 and 10), and self-image (items 16, 21, and 25). All standardized coefficients were significant and of acceptable magnitude. Two covariances were included between items 3 and 18 and between items 6 and 25. The inclusion of covariances and removal of nonsignificant items substantially improved the fit of the model, yielding optimal levels of RMSEA (0.03), CFI (0.97), and TLI (0.96) fit indices. Additionally, the model χ^2 indicated acceptable fit ($\chi^2 = 36.02$, $p = 0.11$). Results yielded a final COHIP-PS instrument consisting of 11 items across four domains (Appendix 6).

Discussion

The COHIP-PS is the first validated instrument created to measure OHRQoL in preschool children using cleft, dental, speech, and community samples. QoL is an integral parameter in understanding, assessing, and ultimately improving preschool children's well-being. The COHIP-PS measures the impact of a child's health status on a variety of QoL domains. Through a multistage development process, items not pertinent or relevant were identified and deleted from the item pool to develop the final questionnaire. Four different samples (cleft, speech, pediatric dental, and community) were sought to determine item clarity, frequency, and importance for this age group. Item elimination was based on statistical and theoretical considerations, particularly an item's relevance to a conceptual model of OHRQoL that has been supported by previous research on children with cleft (Broder *et al*, 2014a).

Reliability testing revealed acceptable internal consistency for the overall COHIP-PS, however alphas were below the set threshold of 0.70 for the community sample (0.66). This finding may suggest that the COHIP-PS may not be as reliable when applied to community samples that include patients without oral conditions. Test-retest findings suggest excellent reproducibility for the overall questionnaire. For clinical severity, analysis found that within pediatric dental participants, severity of difference as measured by dmft was significantly associated with reduced COHIP-PS scores. In contrast, cleft type in the cleft group did not significantly correlate with overall COHIP-PS scores, or any domain scores, with the exception of oral health. It is recommended that extent of difference (EOD) ratings in cleft samples be used for severity ratings, as measured by subjective (e.g., caregiver and child) or objective (surgeon appraisal) perceptions of difference. EOD speech and facial appearance ratings have been previously shown to be sensitive to and associated with COHIP scores, rather than cleft type (Broder *et al*, 2014b; Broder et al., 2016; Long et al., 2016). Future testing of the COHIP-PS should explore the impact of alternatively-measured cleft severity, rather than cleft type, on OHRQoL.

Overall, the COHIP-PS is sensitive to expected differences between clinical conditions. Convergent validity was examined by comparing COHIP-PS scores and global health. Moderate, statistically significant correlations were found within each sample group for the overall COHIP-PS and the oral health and functional well-being domains. In contrast, correlations were not significant for the social-emotional or self-image domains. While such differences may be found among youth, the emerging self-image and social interactive behavior among preschool children may reflect reduced OHRQoL in this younger age group. Thus, the overall significant correlation between general health and COHIP-PS supports the use of the COHIP-PS as a general measure of OHRQoL, though social-emotional and self-image domains may not be as contributory to overall general health in preschool-aged children compared to older children.

Discriminant validity testing revealed that the cleft group had lower COHIP-PS scores than children in the speech, pediatric dental, and community groups. This finding is consistent with existing research on school-aged children with cleft and with well-being measures involving young children with and without health problems (Broder *et al*, 2012a). As expected, the healthy community group had the highest measured COHIP-PS scores. However, despite the overall significant differences, the mean differences between groups were small. Discriminant validity methods were used to test for overall differences across groups, which were confirmed by omnibus test results. However, no post-hoc tests for group by group comparisons were conducted. As a result, the observed mean differences may have statistical significance but may not be clinically relevant. Future studies to estimate minimally important differences are recommended.

Item selection based on item impact assessments were largely based on overall findings averaged across each group. Thus, items that may perform well in subsamples (e.g., dental or cleft samples) but not in the overall sample may have been excluded. Additionally, items were removed not only through item impact but through response frequencies, Rasch model results, and validity analyses. As the end goal was to create a single measure that could be consistently used for patients with a variety of oral conditions, we endeavored to identify items that would be consistent across groups. Limitations of this approach include that the instrument loses some discrimination for individual items, and some condition-specific relevance may be lost. Alternative approaches could consider creating condition-specific versions of the COHIP-PS based on initial item impact assessments that critically evaluated subsample scores for each item. Additionally, items with particularly high impact in specific subgroups (e.g., speech, cleft) may be used as supplementary measures of key outcomes in evaluative studies of these patient groups. Despite this limitation, the final COHIP-PS instrument effectively discriminated across groups and within groups based on condition severity.

Results from confirmatory factor analyses demonstrated that a final, 4-factor model was of very good fit, with moderate to large coefficients for each item per domain. The final COHIP-PS model consisted of oral health, functional well-being, social-emotional well-being, and self-image domains. In contrast, the initial five-factor model of the original COHIP instrument was of inadequate fit, which included an additional factor for school environment. Given the notable differences in school experience comparing pre-school children to school-aged children, this result is understandable. The original COHIP items for school environment included questions on missed school days, difficulty paying attention, reluctance to speak out loud in class, or reluctance to attend school due to teeth, mouth, or facial issues. These items are likely developmentally inappropriate for preschool children, and also may have been difficult to assess from the caregiver perspective, which may explain the poor fit of the original COHIP factor structure. Additionally, poor item loadings led to reduced items within each COHIP-PS domain compared to the original COHIP. This result is likely due to developmental and/or psychosocial differences in preschool versus school-aged children. For example, social-emotional well-being in the initial COHIP instrument included items for bullying, being different, or discomfort with being asked about teeth, mouth, or face. These items are seemingly not salient for preschool-aged children.

Limitations of the study include the use of convenience samples for instrument validation. Additionally, age data were not collected beyond determining study eligibility, which prevents age group comparisons across items or domains. Therefore, future research should use a different sample of caregivers having preschool children with specific oral health conditions, such as cleft, and include age when testing the evaluative properties to better understand the sensitivity of the COHIP-PS to treatment impact over time.

Conclusion

Health service researchers embrace QoL as a crucial parameter in measuring well-being in both adults and children. Given that young children, especially those with chronic conditions, are dependent on their caregivers for consent and treatment adherence, measuring OHRQoL is paramount in family-centered pediatric care (Varni et al., 1999). The COHIP-PS is the first validated measure of OHRQoL for preschool children with varying orofacial conditions, speech and language deficiencies, dental needs, and healthy community participants in the U.S.

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