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Validations of the OM-6 Parent-Proxy Survey for Infants/Toddlers with Otitis Media

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Abstract

Objective: To validate the Otitis Media-6 (OM-6), a parent-proxy quality-of-life (QOL) questionnaire for infants/young children with OM, against other previously validated generic QOL questionnaires.

Study Design: Multi-institutional cross-sectional study.

Setting: 23 otolaryngology, pediatric, and family practices across the United States.

Subjects and Methods: Caregivers of 6–24 months old children with a history of OM completed the OM-6, OM History Form, and PedsQL™ Infant Scales survey. Principal components analysis (PCA) examined the underlying factor structure of items on the OM-6, and Cronbach's alpha measured the internal consistency of items on each factor. Discriminant validity was assessed with receiver operating curves (ROC).

Results: Surveys from 1045 patients were analyzed. The overall OM-6 was strongly to moderately correlated with the Pediatric Quality of Life (PedsQL)™ Infant Scales scores (Pearson $r = -0.649$ for ages 6–12 months and -0.566 for ages 13–24 months). Two underlying constructs, “Behavior and Symptoms” and “Hearing and Speech”, emerged from the PCA. Each factor and the overall OM-6 showed excellent internal-consistency reliability (each Cronbach's $\alpha > 0.75$). The areas under the curve on the ROC analyses were < 0.65 for recurrent and chronic OM using a variety of frequency and chronicity cut-points and definitions.

Conclusion: The OM-6 measures two underlying QOL constructs, Behavior and Symptoms and Hearing/Speech. The overall OM-6 showed acceptably high internal-consistency reliability and good construct validity. However, the ability of the OM-6 to identify children who have more severe clinical recurrent or chronic OM vs. milder disease was not supported by our analysis.

Keywords

Otitis Media; Otitis-Media 6; health-related quality of life; validation

INTRODUCTION

Otitis media (OM) is a common childhood disease; 40% of children with OM will experience recurrent OM (ROM, ≥ 3 acute OM episodes in the past 12 months) or chronic OM (COM, middle ear effusions in one or both ears for ≥ 3 months).^{1, 2} It is the most frequent reason for physician visits, surgery, and antibiotic prescriptions for children in developed countries.^{3, 4} Children suffering from ROM or COM may experience earaches, fevers, crying, sleep disturbances, and interference with normal activities.^{5, 6} ROM or COM can lead to conductive hearing loss that can result in developmental delays.^{2, 7} Consequently, children with ROM or COM may experience lower quality of life (QOL).

Health-related QOL is an important outcome in clinical trials, evaluation of healthcare services, and developing strategies to improve clinical practice.^{8, 9} While functional health status describes the physical, emotional, psychological, or social functioning of a person, QOL measures one's perception of their functional health status.^{2, 10}

The Otitis Media-6 (OM-6) survey is a parent-proxy QOL assessment for children with ROM or COM.¹ The major advantages of the OM-6 are ease of use and conciseness.¹¹ In addition to good test-retest reliability, the OM-6 had good construct validity based on correlations with ear-related global QOL and between individual OM-6 items with clinical measures, such as the number of ear-related physician visits or antibiotic use. The OM-6 change score also correlated with the change in caregiver-reported, ear-related global QOL. However, Rosenfeld et al did not assess discriminant validity, and evaluation of the psychometric properties of the OM-6 is limited.¹ Heidemann et al evaluated psychometric properties and structural validity of a Danish version of the OM-6.¹² They observed moderate correlation between the OM-6 scores and the Child Health Questionnaire (CHQ-PF50), a generic QOL questionnaire for children ages 5–18, although their target population included only children age 0–6 years. Kubba et al also found moderate correlation between the OM-6 and the Health Utilities Index Mark III; they reported that the OM-6 did not adequately discriminate between groups with varying disease severity.¹¹

The objectives of this study were to evaluate the construct validity of the OM-6 questionnaire for children with OM and to explore its underlying factor structure. A measurement has construct validity when it measures what it claims to measure. Construct validity is determined by examining correlations between the measure being tested and other measures of the same construct (convergent validity) as well as the measure's ability to differentiate between groups of children (discriminant validity). Specifically, we sought to examine the construct validity of the OM-6 compared with a validated, parent-proxy QOL measure for infant children with and without ROM or COM, and determine whether the OM-6 would discriminate between children with more and less severe OM.

METHODS

Study Design and Population

This cross-sectional study was conducted at 23 sites, including otolaryngology, pediatrics, and family practice clinics across the United States. The locations of the participating practices were documented in previous publications and are acknowledged in Appendix 1.^{13, 14} In previous publications of this study, we quantified the burden of OM, compared the impact of tympanostomy tubes on infant health-related QOL, and explored the impact and predictability of OM severity on caregiver QOL. The otolaryngology sites were recruited from the BEST-ENT (Building Evidence for Successful Treatments in Otolaryngology) and CHEER (Creating Healthcare Excellence through Education and Research) research networks along with their pediatric and family practice colleagues. The Washington University Medical Center Human Research Protection Office provided institutional review board approval, requiring written informed consent forms from participating physicians and allowing a waiver of written informed consent from caregivers.

Participating sites enrolled caregivers of patients who satisfied the inclusion criteria when they were seen between January 2009 and February 2012. Inclusion criteria at otolaryngology sites were children ages 6 to 24 months presenting with a chief complaint of ROM or COM. Children recruited from family practice or pediatric sites presented for routine wellness visits, regardless of OM history. This allowed us to recruit patients with a wide range of OM severity, not just those with ROM or COM referred to pediatric otolaryngology. The only exclusion criterion was caregivers who were unable to complete the questionnaires in English. Participating caregivers were given a packet of questionnaires to complete at the visit or later with a mail-in option.

Patient and Caregiver Data

Caregivers provided demographic information such as race, insurance status, and family income. Information obtained from a physician-completed patient history form included the patient's OM history and hearing assessment in the past 3 months.

Questionnaires

Caregivers completed the OM-6¹, the Otitis Media History Form,² and Pediatric Quality of Life Inventory™ (PedsQL™) Infant Scales.¹⁵ Only those measures for which at least 50% of the items were answered were included in our analyses.

The OM-6 is a parent-proxy measure of QOL of children with OM.¹ Its 6 questions measure Physical Suffering, Hearing Loss, Speech Impairment, Emotional Distress, Activity Limitations, and Caregiver Concerns. Responses for each item were scored from 1 to 7 (1=Not present/no problem; 2=Hardly a problem at all; 3=Somewhat of a problem; 4=Moderate problem; 5=Quite a bit of a problem; 6=Very much of a problem; 7=Extreme problem). A mean score of all six items comprises the OM Total Score. Higher mean scores of all six items indicate greater severity and impact of OM on the child's QOL.

The Otitis Media History Form is completed by caregivers of children with OM regarding the severity of a child's ear infections.² Severity included the number of times parents were told that their child had an ear infection or ear fluid over the prior 3 months (frequency); the amount of time that an ear infection or ear fluid affected comfort, hearing, sleep, or activities over the prior 3 months; and the number of times that a child received antibiotics for ear infection or ear fluid in the preceding 3 months. In addition to these questions, we asked about frequency of ear infection or ear fluid over the past 1 and 12 months, and the percent of time a child has spent with AOM or OME over the past 1, 3, and 12 months.

The PedsQL™ Infant Scales measure the parent's perception of the QOL of infants, with one form for ages 1–12 months and another for ages 13–24 months.¹⁵ The 1–12 month version has 36 items and contains 5 domains: Physical Functioning, Physical Symptoms, Emotional Functioning, Social Functioning, and Cognitive Functioning. The survey for ages 13–24 months old has 45 items within the same 5 domains. Response options for each item use a 5-point scale (0=never a problem; 1=almost never a problem; 2=sometimes a problem; 3=often a problem, 4=almost always a problem). Each item is then reverse scored and converted to a 0–100 scale, so that higher scores indicate better QOL. Mean overall and subscale scores are computed as the sum of item responses divided by the number of items answered. The Physical Health Summary score averages the item responses from the Physical Functioning and Physical Symptom Scales. The Psychosocial Health Summary score averages the Emotional, Social, and Cognitive Functioning Scales.

Appendix 2 describes these questionnaires in further detail.

Statistical Analysis

Statistical analyses were conducted using SPSS software v.23 (IBM Corporation, Armonk, New York). We used exploratory principal components analysis (PCA) with varimax rotation to determine the underlying factor structure of the OM-6.^{16, 17} For the PCA criterion for factor identification, we used an iterative process of analysis, utilizing an eigenvalue >1.000. The internal consistency of items loading on any underlying factors and on the entire OM-6 was evaluated using Cronbach's α coefficient.¹⁸ Streiner and Norman recommend that for health measurement scales, Cronbach's α should be above 0.70¹⁹ (p. 65)

Descriptive statistics (frequency counts and percentages, means and standard deviations [SD]) were calculated for each demographic factor. Bivariate analysis of construct validity of OM-6 and factor component scores used Pearson's r correlation coefficient to compare with the PedsQL™ Infant Scale. We interpreted Pearson r values of <0.2 to be very weak correlations, 0.2 to 0.39 as weak, 0.4 to 0.59 to be moderate, 0.6 to 0.79 to be strong, and 0.8 to 1.0 to be very strong correlations.²⁰ We expected the OM-6 to correlate moderately with the PedsQL™ Infant Scale. Independent-samples t-tests and analyses of variance (ANOVA) were used to assess between-groups differences in overall OM-6 scores and factor scores with 95% confidence intervals (CI) reported. Post-hoc pairwise differences were analyzed using Tukey's HSD. Statistical significance was set at a 2-tailed $p < 0.05$. Confidence intervals are statistically significant when the 95% CI around a difference between groups does not include 0.

Discriminant validity was assessed with receiver operating curves (ROC) and comparison of area under the curves (AUC). An AUC of 1.0 is interpreted as perfect discrimination, whereas an AUC of 0.5 demonstrates no ability to discriminate. We used different cut-points for severity (e.g., frequency of diagnosed infections) to differentiate between those children with and without more severe OM disease.

RESULTS

Demographics

The 23 participating sites enrolled 2413 children in the study; we included in our analysis 1045 parents who completed the OM-6 and at least one other questionnaire, most of whom (90.8%) were enrolled from otolaryngology practices. The average age of the children was 15 months (range 6–24 months). Additional demographic information is found in Table 1.

Principal Components Analysis and Internal Consistency

Exploratory PCA of the OM-6 items resulted in a 2-factor solution; items showed high factor loadings (i.e., correlations among items within each factor) on one of the two factors (Table 2). Items measuring Physical Suffering, Emotional Distress, Activity Limitations, and Caregiver Concerns were highly correlated with each other and loaded onto a factor named “Behavior and Symptoms” (BaS). Items measuring Hearing Loss and Speech Impairment were highly correlated with each other and loaded onto a factor named “Hearing and Speech” (HaS). The factor BaS explained 57% of the total variance in OM-6 factor structure, and the factor HaS explained an additional 21% of the total variance. The internal consistencies of the overall OM-6 survey and factors are shown on Table 3. Cronbach’s α values were high (> 0.70) for all OM-6 versions (i.e., both 1–12 and 13–24 month age groups).¹⁸

Construct Validity

The correlations of the OM-6 and the two underlying factors (BaS and HaS) with the PedsQL Infant Scales are shown in Table 4. The overall OM-6 score was strongly to moderately negatively correlated with the PedsQLTM Infant Scales scores (Pearson $r = -0.649$ for ages 6–12 months and -0.566 for ages 13–24 months, $p < 0.001$ for each). However, the overall OM-6 score was weakly to moderately correlated with the individual five domains from the PedsQLTM Infant scales. The overall OM-6 score was highly collinear with BaS (Pearson $r = 0.940$, $p < 0.001$) and strongly correlated with HaS (Pearson $r = 0.656$, $p < 0.001$) subscales, while the correlation between BaS and HaS was moderate (Pearson $r = 0.362$, $p < 0.001$).

The BaS subscale scores moderately correlated with the Physical and Psychosocial Summary scales for both age groups, and weakly to moderately correlated with the individual five domains from the PedsQLTM Infant scales. The correlations between the HaS subscale scores and the PedsQL Infant Scales were weaker overall than for BaS. Despite weaker correlations, all Pearson r coefficients were statistically significant.

Discriminant Validity

We defined ROM as ≥ 3 acute OM episodes in the past 12 months and COM as the presence of middle ear effusions in one or both ears for ≥ 3 months as denoting more severe OM. For ROM, the AUC for total OM-6 score was 0.623, 0.602 for BaS, and 0.607 for HaS (Figure 1A). For COM, the AUC for total OM-6 score was 0.645, 0.621 for BaS, and 0.638 for HaS (Figure 1B). When we investigated other cut-points for more severe OM (e.g., ≥ 4 acute OM episodes, or presence of middle ear effusion for ≥ 6 months), the AUC values decreased, showing even poorer discrimination.

The OM-6 scores did show some ability to discriminate those with any OM vs. none, with receipt of ≥ 1 course of antibiotics for ear infection or ear fluid in the preceding 3 months having an AUC of 0.840 for OM-6 total, 0.867 for BaS, but 0.621 for HaS. In addition, total OM-6 had an AUC of 0.858 for “small amount of time” or more that ear infections or ear fluid affected comfort, hearing, sleep, or activities over the prior 3 months, and 0.886 for BaS, but 0.621 for HaS.

Influence of Demographic and Clinical Variables on OM-6 Scores

Table 5 shows the influence of demographic and clinical variables on overall OM-6 score and its subscales. The overall OM-6 scores did not differ significantly between the two age groups. However, children ages 6–12 months had higher scores (poorer outcomes) on BaS than children ages 13–24 months (mean difference=0.4, 95% CI 0.1 to 0.5), whereas children ages 13–24 months had higher scores on HaS than children ages 6–12 months (mean difference=0.6, 95% CI 0.4 to 0.8). Children who attended daycare at least part-time scored lower on HaS (mean difference=0.2, 95% CI 0.01 to 0.4) than children who did not attend daycare, but there was no difference in overall OM-6 scores or BaS scores. ANOVA showed statistically significant differences in BaS scores among income groups; in post-hoc analysis, children from families with an income of \$20,000–39,999 had worse BaS subscale scores than children from families with an income of \$100,000 or higher (mean difference=0.5, 95% CI 0.25 to 0.94). Children recruited from at an otolaryngology clinic had higher overall OM-6 (mean difference=0.9, 95% CI 0.60 to 1.21), BaS (mean difference=1.0, 95% CI 0.62 to 1.36), and HaS scores (mean difference=0.7, 95% CI 0.48 to 0.95) than children recruited from a family or pediatric practice. There were no differences between overall OM-6 scores or either component by sex, race, ethnicity (Hispanic vs non-Hispanic), or maternal or paternal education status.

We analyzed data from 968 caregivers who reported whether the child had received ear tubes. Children with no history of ear tubes had higher overall OM-6 score (mean 3.3 vs 2.8, mean difference=0.5, 95% CI 0.30 to 0.72) and BaS scores (mean 3.9 vs 3.2, mean difference=0.7, 95% CI 0.48 to 1.00) than children with ear tubes. Physicians reported the hearing status on 535 patients. Among these patients, children with any hearing loss had higher overall OM-6 (mean 3.5 vs 2.9, mean difference=0.6, 95% CI 0.38 to 0.82), BaS (mean 3.9 vs 3.4, mean difference=0.5, 95% CI 0.21 to 0.72) and HaS (mean 2.7 vs 1.9, mean difference=0.8, 95% CI [0.61 to 1.11]) scores than children with normal hearing.

DISCUSSION

As expected, the overall OM-6 scores correlated moderately to strongly with the overall PedsQL Infant Scale scores. PCA analysis revealed two underlying factors in the overall OM-6, BaS and HaS, which individually correlated moderately to strongly with the PedsQL Infant Scale scores. Items on the OM-6 and its two components showed excellent internal-consistency reliability. These results were consistent with good convergent validity and with caregivers' perceptions. However, the ability of the OM-6 to identify children who have more severe clinical ROM or COM vs. milder disease was not supported by our analysis, agreeing with Kubba et al.¹¹

The BaS scores correlated moderately to strongly with the PedsQL™ subscale scores related to physical and emotional suffering. HaS correlated moderately for the 6–12 month olds versus strongly for the 13–24 month olds with the Cognitive Functioning subscale score of the PedsQL™ Infant Scale. Rosenfeld et al concluded that caregiver assessment of their child's hearing is not very precise.²¹ Similarly, generic QOL questionnaires do not specifically measure hearing- or speech-related dimensions of QOL. Because children develop speaking and communication skills rapidly between the ages of 1 and 2 years,²² speech and hearing may concern parents of 1–2 year-old children more than younger children, resulting in worse HaS scores for the older age group. In contrast, the children 6–12 months old had worse BaS scores than children 13–24 months old. Parents of 6–12 month-old children may be more anxious about their child's pain and suffering than their child's hearing and speech. The mean differences in BaS and HaS scores between the two ages were 0.4 and 0.6 respectively. These differences approximate one-third of the pooled SD, constituting a small effect size. Therefore, it is difficult to gauge how important these differences are clinically.

Children in daycare scored slightly better on HaS. Because children in daycare receive regular social interaction and teacher engagement, with some faculty with training in early childhood development, these factors can positively influence the child's QOL. Families with incomes of \$20,000–39,000 had worse BaS scores than families with an incomes over \$100,000. Caregivers with lower income may lack the resources that can improve their child's QOL. However, there were no other significant differences in BaS scores between the other income groups and differences in these comparisons were small.

Patients seen and recruited at otolaryngology clinics had worse overall OM-6, BaS, and HaS scores compared to those from family and pediatric practices. We expected patients from otolaryngology clinics would have more severe OM on all three measurements. Also, a visit with primary care may focus less on their child's OM and be more relaxed, without delving into the severity of OM, hearing loss, and other aspects that could negatively impact a caregiver's perception of their child's QOL.

Two subgroups of children displayed significant differences in OM-6 scores. Children with one or more sets of ear tubes had better OM-6 and BaS scores. The mean difference was larger on the BaS scores, suggesting that physical and emotional suffering were alleviated

with ear tubes more than hearing and speech concerns. Children with any hearing loss had worse OM-6, BaS, and HaS scores, with HaS showing the largest mean difference.

There were several important limitations in this study. The design was cross-sectional, not longitudinal, and otoscopic exams did not verify the parent-reported diagnosis of acute OM or OME. This introduces an unknown degree of error in the measurement of clinical severity. We were unable to use over half of the surveys collected due to incomplete data collection; therefore, self-selection bias may have affected our results. The majority of our patient population was white and male, and 56% of households earned \$60,000 annually, above the 2014 U.S. median household income of \$53,657.²³ Most caregivers were well-educated, with 59% of mothers and 47% of fathers possessing at least a bachelor's degree compared to 33% of women and 32% of men in the general population.²⁴ In addition, we excluded caregivers who could not complete the questionnaire in English because we did not have the resources to provide written translations of the OM-6 and the other surveys into multiple languages. In-person translators were not used due to the cost and variability in the skill and training between translators and sites, which adds further uncontrolled bias. These factors may limit the generalizability of our study.

Ultimately, the OM-6 showed convergent validity when correlated against generic QOL questionnaires but poor discriminant validity for more severe ROM or COM. The moderate correlations reflect that the OM-6 measures different dimensions of a child's experience with OM that are not captured with generic QOL questionnaires. Although the OM-6 takes into account OM-related QOL in children, it cannot be considered a surrogate for clinical measures of OM severity such as frequency and chronicity of OM.

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PedsQL™: Dr. James W. Varni holds the copyright and the trademark for the Pediatric Quality of Life Inventory™.

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Appendix 1, Participating Sites

The authors would like to acknowledge the following clinics and medical centers for their assistance with patient enrollment and recruitment: Washington University School of Medicine, St. Louis, Missouri; Coastal Ear, Nose and Throat, New Jersey; Otolaryngology Consultants of Memphis, Tennessee; Park Nicollet Clinic, Minnesota; Peyton Manning Children's Hospital Ear, Nose and Throat Center, Indianapolis, Indiana; Boys Town Ear, Nose & Throat Institute, Omaha, Nebraska; ENT & Allergy Associates, LLP, New York and New Jersey; Frisco Family (formerly McKinney ENT), McKinney, Texas; Advanced ENT & Allergy (formerly Commonwealth ENT), Kentucky; Medical University of South Carolina; David John Bailey, MD, PA; John Hopkins School of Medicine, Department of Otolaryngology–HNS, Division of Pediatric Otolaryngology, Baltimore, Maryland; Medical College of Wisconsin, Children's Hospital of Wisconsin; University of Texas Medical

Branch; Summit Medical Group, New Jersey; University of Kansas Pediatric Otolaryngology; University of Michigan, Ann Arbor, Michigan; Mayo Clinic; Caryn Garriga, MD, LLC (formerly Chesterfield Pediatrics), Chesterfield, Missouri; Tots Thru Teens Pediatric, Missouri; Pediatric Healthcare Unlimited, Alton, Illinois; and Fenton Pediatrics, Fenton, Missouri.

Appendix 2, Description of Measures Used

Otitis Media-6 (OM-6)¹ survey is a parent-proxy QOL assessment tool for children with OM. The OM-6 is comprised of 6 questions measuring Physical Suffering, Hearing Loss, Speech Impairment, Emotional Distress, Activity Limitations, and Caregiver Concerns. Responses for each item were scored from 1 to 7 (1=Not present/no problem; 2=Hardly a problem at all; 3=Somewhat of a problem; 4=Moderate problem; 5=Quite a bit of a problem; 6=Very much of a problem; 7=Extreme problem). A mean score from all questions comprise the OM Total score. Higher mean scores of all six items indicate greater severity and impact of OM on the child and poorer disease-specific QOL

The **Otitis Media History Form** is a survey that caregivers of children with OM completed regarding the severity of a child's ear infections based on several different criteria.² Severity included the number of times parents were told that their child had an ear infection or ear fluid over the prior 3 months; the amount of time that an ear infection or ear fluid affected comfort, hearing, sleep, or activities over the prior 3 months; and the number of times that a child received antibiotics for ear infection or ear fluid in the preceding 3 months.

Pediatric Quality of Life InventoryTM (PedsQLTM) Infant Scales¹⁵

The PedsQL Infant Scales are a parent-proxy generic QOL assessment for children 1–24 months of age. The 36-item PedsQLTM Infant Scales 1–12 months Version encompasses 5 scales: (1) Physical Functioning (6 items), (2) Physical Symptoms (10 items), (3) Emotional Functioning (12 items), (4) Social Functioning (4 items), and (5) Cognitive Functioning (4 items). The 45-item PedsQLTM Infant Scales 13–24 months Version contains the same 5 scales and the same 36 items as the 1–12 months Version with 9 additional age-appropriate items: (1) Physical Functioning (9 items), (2) Physical Symptoms (10 items), (3) Emotional Functioning (12 items), (4) Social Functioning (5 items), and (5) Cognitive Functioning (9 items). The format, instructions, Likert response scale, and scoring method for the PedsQLTM Infant Scales are identical to the PedsQLTM 4.0 Generic Core Scales for ages 2–18 years, with higher scores indicating better HRQOL. Response options for each item use a 5-point scale (0=never a problem; 1=almost never a problem; 2=sometimes a problem; 3=often a problem, 4=almost always a problem). Each item is then reverse scored and converted to a 0–100 scale, so that higher scores indicate better QOL. Infant Scales 13–24 months Version contains the same 5 scales and the same 36 items as the 1–12 months Version with 9 additional age-appropriate items: (1) Physical Functioning (9 items), (2) Physical Symptoms (10 items), (3) Emotional Functioning (12 items), (4) Social Functioning (5 items), and (5) Cognitive Functioning (9 items). Mean overall and subscale scores are computed as the sum of item responses divided by the number of items answered. The Physical Health Summary score is calculated by taking the sum of item responses in the

Physical Functioning and Physical Symptom Scales divided by the number of items answered. The Psychosocial Health Summary score is computed by taking the sum of item responses in the Emotional, Social, and Cognitive Functioning Scales divided by the total number of items answered.

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1A.

1B.

Figure 1.

Receiver operating characteristics curves for the OM-6 total, Behavior and Symptoms (OM6_BaS) and Hearing and Speech (OM6_HaS), using recurrent otitis media (OM) definition of at least 3 acute OM in 12 months (Figure 1A) and chronic OM definition of at least 3 months of middle ear fluid in 12 months.

Table 1.

Demographics of children and caregivers (n=1045).

Characteristics	Value
Child's age (months), Mean (SD)	15.1 (4.6)
Missing (n, %)	126 (12.1)
Child's sex (n, %)	
Male	593 (56.7)
Female	402 (38.5)
Missing	50 (4.8)
Child's race (n, %)	
White	873 (83.5)
Black or African American	91 (8.7)
Asian	10 (1.0)
American Indian or Alaska Native	3 (0.3)
Native Hawaiian or other Pacific Islander	1 (0.1)
Other	35 (3.3)
Missing	32 (3.1)
Child's Ethnicity (n, %)	
Hispanic	56 (5.4)
Non-Hispanic	757 (72.4)
Missing	232 (22.2)
Education level of mother (n, %)	
7th–9th grade or less	2 (0.2)
9th–12th grade	31 (3.0)
High school graduate	84 (8.0)
Some college or certificate course	289 (27.7)
Associates	1 (0.1)
College Graduate	356 (34.1)
Graduate/professional degree	259 (24.8)
Missing	23 (2.2)
Education level of father (n, %)	
6th grade or less	3 (0.3)
7th–9th grade or less	11 (1.1)
9th–12th grade or less	43 (4.1)
High school graduate	146 (14.0)
Some college or certificate course	269 (25.7)
College graduate	305 (29.2)
Graduate/professional degree	187 (17.9)
Don't know	10 (1.0)

Characteristics	Value
Missing	71 (6.8)
Child's insurance status (n, %)	
None	2 (0.2)
Medicaid	279 (26.7)
Private or employer sponsored	669 (64.0)
Other government insurance	59 (5.6)
Other	2 (0.2)
Missing	34 (3.3)
Income (n, %)	
<\$20,000	148 (14.2)
\$20,000-\$39,999	152 (14.5)
\$40,000-\$59,999	109 (10.4)
\$60,000-\$79,999	166 (15.9)
\$80,000-\$99,999	143 (13.7)
\$100,000 or higher	272 (26.0)
Other	3 (0.3)
Missing	52 (5.0)
Child's Daycare Status (n, %)	
Full-Time	420 (40.2)
Part-Time	218 (20.9)
Not in Daycare	402 (38.5)
Missing	5 (0.5)
Enrollment Site (n, %)	
Pediatric Otolaryngology Site	949 (90.8)
Primary Care Physician Site	71 (6.8)
Missing	25 (2.4)

Table 2.

Factor loadings (i.e., correlations among items on each factor) of OM-6 items on each factor following principal components analysis with varimax rotation.

OM-6 items	Factor 1 Behavior and Symptoms	Factor 2 Hearing and Speech
Physical Suffering	0.858 *	0.136
Hearing Loss	0.245	0.864 *
Speech Impairment	0.098	0.911 *
Emotional Distress	0.843 *	0.233
Activity Limitations	0.873 *	0.134
Caregiver Concerns	0.863 *	0.152

* indicate the items that loaded highly onto each factor and were used to compute scores for OM-6 Behavior and Symptoms or Hearing and Speech subscales

Table 3.

OM-6 Cronbach's alpha coefficients for the OM-6 and factor components for all participants and each age group.

	All participants n = 1045	Ages 6–12 months n =303	Ages 13–24 months n =616
All OM-6 scale items	0.845	0.812	0.867
Behavior and Symptoms items	0.898	0.874	0.912
Hearing and Speech	0.763	0.719	0.773

Table 4.

Pearson correlation coefficients between OM-6 and other measures for all participants.

Quality-of-Life Measures	Overall OM-6	Behavior and Symptoms	Hearing and Speech
PedsQL™ Infant Scale (ages 1–12 months):			
Physical Functioning	−0.656	−0.640	−0.333
Physical Symptoms	−0.460	−0.454	−0.221
Physical Health Summary (mean of 2 scales above)	−0.589	−0.601	−0.303
Emotional Functioning	−0.609	−0.612	−0.267
Social Functioning	−0.339	−0.301	−0.235
Cognitive Functioning	−0.313	−0.223	−0.355
Psychosocial Health Summary (mean of 3 scales above)	−0.612	−0.564	−0.325
Total Scale Score	−0.649	−0.628	−0.341
PedsQL™ Infant Scale (ages 13–24 months)			
Physical Functioning	−0.539	−0.563	−0.261
Physical Symptoms	−0.362	−0.388	−0.154
Physical Health Summary (mean of 2 items above)	−0.505	−0.533	−0.233
Emotional Functioning	−0.511	−0.557	−0.194
Social Functioning	−0.270	−0.246	−0.203
Cognitive Functioning	−0.412	−0.281	−0.523
Psychosocial Health Summary (mean of 3 scales above)	−0.54	−0.502	−0.395
Total Scale Score	−0.566	−0.553	−0.358

Note: Higher OM-6 Scores indicate a worse quality of life whereas higher PedsQL™ Infant Scales Scores indicate a better quality of life. Therefore, the correlations are negative.

All correlations are statistically significant ($p < 0.001$).

Table 5.

Bivariate analysis of OM-6 overall and subscores associated with demographic variables. Higher scores indicate higher levels of concern or problem. P values for the overall comparison between variable categories are provided in the same row as the variable name.

Variable	Overall OM-6, mean (SD)	Behavior and Symptoms, mean (SD)	Hearing and Speech, mean (SD)
Child's Age	<i>p</i> =0.743	<i>p</i> =0.001	<i>p</i> <0.001
6–12 months	3.23 (1.09)	3.98 (1.39)	1.71 (1.05)
13–24 months	3.20 (1.34)	3.64 (1.59)	2.30 (1.45)
Child's Sex	<i>p</i> =0.212	<i>p</i> =0.306	<i>p</i> =0.415
Male	3.26 (1.25)	3.79 (1.50)	2.17 (1.42)
Female	3.16 (1.32)	3.69 (1.60)	2.10 (1.37)
Child's Race	<i>p</i> =0.844	<i>p</i> =0.729	<i>p</i> =0.112
White	3.22 (1.26)	3.75 (1.53)	2.13 (1.37)
Black or African American	3.20 (1.39)	3.72 (1.62)	2.16 (1.49)
Asian	2.72 (1.17)	3.18 (1.60)	1.80 (1.03)
American Indian or Alaska Native	3.56 (1.87)	3.17 (2.13)	4.33 (1.61)
Native Hawaiian or other Pacific Islander (No SD, n=1)	3.83	5.25	1.0
Other	3.18 (1.23)	3.74 (1.51)	2.06 (1.48)
Child's Ethnicity	<i>p</i> =0.903	<i>p</i> =0.976	<i>p</i> =0.851
Hispanic	3.22 (1.33)	3.77 (1.73)	2.13 (1.40)
Non-Hispanic	3.24 (1.27)	3.77 (1.52)	2.16 (1.40)
Daycare	<i>p</i> =0.523	<i>p</i> =0.793	<i>p</i> =0.029
No	3.24 (1.30)	3.73 (1.53)	2.26 (1.50)
Part-time	3.28 (1.29)	3.81 (1.54)	2.19 (1.48)
Full-time	3.17 (1.24)	3.73 (1.53)	2.00 (1.23)
Maternal education level	<i>p</i> =0.727	<i>p</i> =0.566	<i>p</i> =0.381
7th-9th grade or less (n=2)	3.67 (0.00)	4.63 (0.53)	1.75 (1.06)
9th-12th grade	3.19 (1.09)	3.71 (1.38)	2.13 (1.51)
High school graduate	3.32 (1.35)	3.99 (1.65)	1.95 (1.39)
Some college or certificate course	3.31 (1.25)	3.82 (1.52)	2.28 (1.46)
Associates (No SD, n=1)	3.33	3.75	2.50
College Graduate	3.15 (1.25)	3.69 (1.50)	2.05 (1.32)
Graduate/professional degree	3.17 (1.31)	3.66 (1.55)	2.18 (1.42)
Income	<i>p</i> =0.052	<i>p</i> =0.044	<i>p</i> =0.585
<\$20,000	3.22 (1.26)	3.75 (1.58)	2.13 (1.41)
\$20,000-\$39,999	3.52 (1.23)	4.12 (1.44)	2.32 (1.55)
\$40,000-\$59,999	3.26 (1.41)	3.79 (1.76)	2.17 (1.42)
\$60,000-\$79,999	3.08 (1.25)	3.61 (1.49)	1.99 (1.30)

Variable	Overall OM-6, mean (SD)	Behavior and Symptoms, mean (SD)	Hearing and Speech, mean (SD)
\$80,000-\$99,999	3.15 (1.26)	3.64 (1.50)	2.14 (1.36)
\$100,000	3.14 (1.24)	3.64 (1.47)	2.15 (1.37)
Other	3.67 (1.76)	4.33 (2.08)	2.33 (2.31)
Enrollment site	$p<0.001$	$p<0.001$	$p<0.001$
Pediatric otolaryngology	3.29 (1.26)	3.82 (1.51)	2.19 (1.41)
Primary care	2.38 (1.17)	2.83 (1.49)	1.47 (0.92)