# The PedsQL™* 4.0 as a Pediatric Population Health Measure: Feasibility, Reliability, and Validity

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***Background.—***The application of health-related quality of life (HRQOL) as a pediatric population health measure may facilitate risk assessment and resource allocation, the tracking of community health, the identification of health disparities, and the determination of health outcomes from interventions and policy decisions.

***Objective.—***To determine the feasibility, reliability, and validity of the 23-item PedsQL 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales as a measure of pediatric population health for children and adolescents.

***Design.—***Mail survey in February and March 2001 to 20 031 families with children ages 2–16 years throughout the State of California encompassing all new enrollees in the State's Children's Health Insurance Program (SCHIP) for those months and targeted language groups.

***Methods.—***The PedsQL 4.0 Generic Core Scales (Physical, Emotional, Social, School Functioning) were completed by 10 241 families through a statewide mail survey to evaluate the HRQOL of new enrollees in SCHIP.

***Results.—***The PedsQL 4.0 evidenced minimal missing responses, achieved excellent reliability for the Total Scale Score ($\alpha$ = .89 child; .92 parent report), and distinguished between healthy children and children with chronic health conditions. The PedsQL 4.0 was also related to indicators of health care access, days missed from school, days sick in bed or too ill to play, and days needing care.

***Conclusion.—***The results demonstrate the feasibility, reliability, and validity of the PedsQL 4.0 as a pediatric population health outcome. Measuring pediatric HRQOL may be a way to evaluate the health outcomes of SCHIP.

**KEY WORDS:** adolescents; children; health; health-related quality of life; pediatrics; PedsQL; population health; SCHIP; State Children's Health Insurance Program

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Health-related quality of life (HRQOL) measurement has emerged as an important health outcome in clinical trials, clinical practice improvement strategies, and health care services research and evaluation.[1–3] Health status, functional status, and HRQOL are terms often used interchangeably; however, a meta-analysis suggests that a more conceptually definitive distinction between these terms is warranted.[4] Health status and functional status refer to the physical functioning dimension of the broader HRQOL construct, while the HRQOL construct additionally includes the psychosocial dimensions of emotional, social, and role functioning, as well as related constructs. Thus, a HRQOL instrument must be multidimensional, consisting at the minimum of the physical, mental, and social health dimensions delineated by the World Health Organization.[5]

During the past 20 years, HRQOL has been primarily measured in adult and pediatric chronic health conditions with relatively small sample sizes.[2,6,7] In recent years, HRQOL has begun to be explored as an outcome measure in large adult population-based surveys. For example, the potential of HRQOL as an adult population health measure has been investigated with the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)[8] and the 12-Item Short-Form Health Survey (SF-12).[9] These investigations have studied the feasibility of the SF-36 and SF-12 as population health measures by examining the percentage of missing responses, internal consistency reliability, and validity using the known groups methodology, where, for example, the SF-36 was shown to discriminate among population groups known to have different levels of health (healthy vs self-reported chronic health problems),[8,10] and for screening populations to identify high-risk groups and risk factors.[11] The Centers for Disease Control and Prevention (CDC) has also incorporated HRQOL as an adult population measure in recent years.[12]

HRQOL may be a particularly appropriate outcome measure of pediatric population health, as mortality is not a sufficiently sensitive outcome in children older than one, except in accidents.[13] The other traditional outcome, morbidity, is also difficult to use for pediatric population health measurement because the large number of relatively rare chronic disorders in pediatric epidemiology make it difficult to aggregate symptoms across conditions.[13,14] School absence, another way of measuring morbidity, has been criticized as being an unreliable indicator of illness

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and as having illness and nonillness (eg, social, behavioral) components.[15,16] Further, most children are quite healthy,[13,14] typically experiencing minor or recurrent illnesses that do not require hospitalization and that resolve within a relatively short time frame.[17] Fewer than 5% of children experience the chronic health conditions manifested in adulthood.[14] The low prevalence of most pediatric chronic health conditions often renders less than ideal population-based health services effectiveness evaluations that are condition based.[17] Meaningful child health outcomes include not only condition-specific symptoms but also broader health concerns, such as physical, emotional, social, and school functioning.[18] Thus, traditional measures of morbidity and mortality may be too narrow in focus to accurately measure health in the general population.[8]

Measuring HRQOL in large pediatric populations has several distinct benefits. It can aid in identifying subgroups of children who are at risk for health problems, in determining the burden of a particular disease or disability, and in informing efforts aimed at prevention and intervention.[19] In addition, utilization of HRQOL measures may assist in the evaluation of the health care needs of a community, and results can be used to influence public policy decisions, including the development of strategic health care plans, identifying health disparities, promoting policies and legislation related to community health, and aiding in the allocation of health care resources.[12] While the importance of measuring pediatric HRQOL in clinical trials is increasingly recognized for children with chronic health conditions,[7] the utility of pediatric HRQOL measurement in population health outcome evaluation has not been fully investigated.

Consequently, this study investigates the feasibility, reliability, and validity of the Pediatric Quality of Life Inventory Version 4.0 (PedsQL 4.0) Generic Core Scales as a pediatric population health outcome in a large, diverse statewide sample of State Children's Health Insurance Program (SCHIP) enrollees in California. The PedsQL 4.0 Generic Core Scales were developed as a generic pediatric HRQOL instrument to be utilized across diverse pediatric populations, including healthy children and children with acute and chronic health conditions.[20–30] Although there are a number of pediatric HRQOL instruments available,[6,7,31,32] the PedsQL 4.0 was selected for the State of California's SCHIP evaluation because of the State's preference for the PedsQL's brevity (only 23 questions are asked), the time required to complete the survey (less than 5 minutes), and the range of ages the survey supports (ages 2–18), in addition to its documented reliability, validity, sensitivity, and responsiveness to changes in HRQOL in healthy children and children with acute and chronic health conditions in smaller, local samples of children and adolescents.[20–30] SCHIP provides a relatively unique opportunity to measure pediatric population health in a large, racially and ethnically diverse population of children and adolescents with significant policy implications.[33]

We hypothesized that the PedsQL 4.0 would distinguish between healthy children and children with chronic health conditions, based on previous PedsQL 4.0 findings,[21–30] and that problems with access to health care would be associated with lower PedsQL 4.0 scores, based on health care plan studies with the SF-36[34] and the Access Pathway Model.[33] We also explored potential minimal clinically important difference values and cut-off point scores for designating an at-risk status for impaired HRQOL, as well as age, gender, language, and race/ethnicity subgroup analyses.

## METHODS

### Sampling Frame

The PedsQL 4.0 survey was mailed separately for each of the months of February and March 2001 to 20 031 families with children ages 2–16 years throughout the State of California, which encompassed all new enrollees in SCHIP for those months and for those ages and for parents and/or children who were English, Spanish, Vietnamese, Korean, or Cantonese speaking. Although the PedsQL 4.0 can be administered to children ages 2–18, children older than 16 years of age were not included in this field test because a 2-year follow-up will be conducted (the oldest children in the sample will be 18 years old at the 2-year follow-up). The mail survey mode of administration was paper-and-pencil self-administration for parents and children ages 8–16, and parent-assisted administration for children ages 5–7.

### Measures

#### *The PedsQL 4.0*

The 23-item PedsQL 4.0 Generic Core Scales encompass 1) Physical Functioning (8 items), 2) Emotional Functioning (5 items), 3) Social Functioning (5 items), and 4) School Functioning (5 items), and were developed through focus groups, cognitive interviews, pretesting, and field-testing measurement development protocols.[20,21]

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 parents' 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 5-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). To further increase the ease of use for the young child self-report (ages 5–7), the response scale is reworded and simplified to a 3-point scale (0 = not at all a problem; 2 = sometimes a problem; 4 = a lot of a problem), with each response choice anchored to a happy to sad faces scale.[35,36] Parent proxy-report also includes the toddler age range (ages 2–4), which does not include a self-report

form given developmental limitations on self-report for children younger than 5 years of age,[36,37] and includes only 3 items for the School Functioning Scale.

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.[38] 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,[20–30] as well as other well-established HRQOL measures.[39,40] For this study, over 98% of child and parent respondents were included in the scale-score analyses after imputing missing values. The Physical Health Summary Score (8 items) is the same as the Physical Functioning Subscale. 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 Subscales.

The PedsQL Measurement Model[20] emphasizes the child's perceptions. The items chosen for inclusion were derived from the measurement properties of the child self-report scales, while the parent proxy-report scales were constructed to directly parallel the child self-report items. The items selected for the PedsQL 4.0 reflect those that are of universal concern across childhood age groups. Attempts were made to keep wording, and thus the content, as similar as possible across parallel forms, while being sensitive to developmental differences in cognitive ability. This consistency facilitates the evaluation of differences in HRQOL across and between age groups, as well as the tracking of HRQOL longitudinally. The PedsQL 4.0 is the only generic pediatric HRQOL measurement instrument of which we are aware to span ages 2–18 for parent proxy-report and ages 5–18 for child self-report while maintaining item and scale-construct consistency.[6,7,31,32]

*Additional Survey Items*

The parents completed 13 additional survey items. The additional survey items were adapted from the PedsQL Family Information Form,[21] the Parent's Perceptions of Primary Care (P3C),[41] a measure of parents' experiences of pediatric primary care quality, and the Consumer Assessment of Health Plans Study (CAHPS),[42] a measure of health plan performance from the consumer's perspective. For the purposes of this investigation, we examined the relationship between the PedsQL 4.0 and two questions on the survey regarding health care access (''In the last 12 months, how much of a problem, if any, was it to get care for your child that you or a doctor believed necessary?'' and ''In the past 12 months, has there been any time when you thought your child should get medical care, but did not?''), and one question on the presence of a chronic health condition (''In the past 6 months, has your child had a chronic health condition?'') defined as a physical or mental health condition that has lasted or is expected to last at least 6 months and interferes with the child's activities. If the parents check ''Yes'' to this question, they were asked ''Which of the following chronic illnesses does your child suffer from?'' The list provided consisted of asthma, diabetes, attention deficit hyperactivity disorder (ADHD), depression, and other (write in). Parents were also asked how many days in the past 30 days their child missed school due to physical or mental health, was sick in bed or too ill to play, and needed someone to care for him or her due to physical and mental health.

## Procedures

Electronic Data Systems (EDS) performed a welcome call, under contract with the state, in which parents were asked questions regarding the SCHIP enrollment process. Also embedded in this welcome call was notification that a brief survey would be mailed to families asking them about their child's health. Parents were informed that their answers to the survey would be kept completely confidential and would not affect their benefits in any way.

DataStat, a nationally recognized survey administration firm located in Michigan, was contracted by the researchers to administer the California statewide mail survey. DataStat mailed the PedsQL 4.0 survey, together with a cover letter, to all eligible SCHIP families in February and March 2001. Inclusion criteria were new enrollee in the State of California SCHIP in the months of February and March 2001, child ages 2–16, and parent and/or child English, Spanish, Vietnamese, Korean, or Cantonese speaking. Parents and children were instructed in the cover letter to complete the PedsQL 4.0 separately, except for children ages 5–7, who were assisted by their parents after the parent completed the proxy report. Parents were also instructed to complete the additional survey items after completing the PedsQL 4.0. In order to assure the anonymity and confidentiality of the respondents' answers and the neutrality of the organization gathering the data, all surveys were mailed back to DataStat. Because the intent of this project was program evaluation and not research, parents and children did not complete informed consent forms. Consequently, deidentified data were analyzed for this report by the investigators. This protocol of analyzing existing deidentified data was approved by the Institutional Review Board at Children's Hospital and Health Center, San Diego.

## Statistical Analysis

The feasibility of the PedsQL 4.0 as a population health measure was determined from the percentage of missing values for each item.[43,44] Scale internal consistency reliability was determined by calculating Cronbach's coefficient alpha.[45] Scales with reliabilities of .70 or greater are recommended for comparing patient groups, while a reliability criterion of .90 is recommended for analyzing individual patient scale scores.[46,47]

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, groups differing in known health status (healthy vs chronic health conditions) were computed[48,49] using *t* tests. Based on previous findings,[21–30] we anticipated that healthy children would report higher PedsQL 4.0 scores than children with chronic health conditions. Also based on previous findings,[21] we anticipated that children who missed more days from school, were more often sick in bed and too ill to play, and more often needed someone to care for them, would report lower scores.

Construct validity was further assessed through comparing PedsQL 4.0 scores with indicators of health care access (questions 6 and 7 on the survey; ''In the last 12 months, how much of a problem, if any, was it to get care for your child that you or a doctor believed necessary?'' scored as not a problem versus a problem; and ''In the past 12 months, has there been any time when you thought your child should get medical care, but did not?'' scored yes or no). It was hypothesized that problems with access to health care would be associated with lower PedsQL 4.0 scores, based on health care plan studies with the SF-36[34] and the Access Pathway Model.[33]

In order to determine the magnitude of the differences between healthy children and children with chronic health conditions, between problems getting care versus no problems getting care, and between receiving care when needed versus not receiving care when needed, effect sizes were calculated.[50] Effect size as utilized in these analyses was calculated by taking the difference between the healthy sample mean and the chronic health condition sample mean, divided by the healthy sample standard deviation. Effect sizes for problems getting care versus no problems getting care were calculated by taking the difference between the ''no problems'' getting care sample mean and the ''yes problems'' getting care sample mean, divided by the ''no problems'' getting care sample standard deviation. Effect sizes for receiving medical care when needed versus not receiving medical care when needed were calculated by taking the difference between the ''got medical care'' sample mean and the ''did not get medical care'' sample mean, divided by the ''got medical care'' sample standard deviation. Effect sizes for differences in means are designated as small (.20), medium (.50), and large (.80) in magnitude.[50]

Chi-square analyses were conducted to explore differences between the chronic health condition sample and the healthy sample for the questions regarding problems getting care versus no problems getting care and between receiving care when needed versus not receiving care when needed. We hypothesized that parents of children with a chronic health condition would report greater problems getting care and receiving care when needed than parents of healthy children. Analyses were performed using a *t* test for independent samples.

The minimal clinically important difference (MCID) for PedsQL 4.0 scale scores was explored through calculating the Standard Error of Measurement (SEM).[51] MCID has been defined as the smallest difference in a score of a domain of interest that patients perceive to be beneficial and that would mandate, in the absence of troublesome side effects and excessive costs, a change in the patient's management.[52] The SEM has been linked to the MCID, in which one SEM identified the MCID in responsiveness in a HRQOL measure, with excellent agreement between the SEM and MCID shown.[53]

We used multivariate linear regression to test whether children experiencing problems getting care or children with foregone care still had lower PedsQL scores after controlling for chronic health condition status, race/ethnicity, and language.

We explored cut-off points for at-risk status for impaired HRQOL by examining the PedsQL 4.0 scale scores for 1 SD (standard deviation) below the mean of the total population sample. Scores approximating 1 SD below the mean were designated as indicating an ''at-risk'' status for impaired HRQOL relative to the population means.[26]

The concordance between child self-report and parent proxy-report was determined through Pearson Product Moment correlation coefficients. Effect sizes for correlations are designated as small (.10), medium (.30), and large (.50).[50] Statistical analyses were conducted using SPSS for Windows.[54]

## RESULTS

### Sample Characteristics

The overall return rate was 51% (10 241 families completed and returned the survey). A minimum response rate of 40% has previously been recommended as achievable for Medicaid surveys using the CAHPS 1.0,[55] with a 56% response rate achieved with a combination of a mail survey followed by telephone interviews.[56] The response rate achieved was expected for the mode and method of survey administration utilized in this survey project, which involved a one-time only mailing.[57] Questionnaires were administered in 5 languages: English (n = 4399, 43.0%), Spanish (n = 5193, 50.7%), Vietnamese (n = 145, 1.4%), Korean (n = 171, 1.7%), and Chinese (n = 333, 3.2%).

We explored potential differences between respondents and nonrespondents for gender, language of questionnaire, and race/ethnicity. Crosstabulations revealed no relationship between response status and gender. There was a significant association between language of questionnaire and response status ($\chi^2 = 383.9$, $P < .001$). Families who were mailed the questionnaires in English were less likely to respond (44.4% responded), and families who were mailed the questionnaire in Spanish were more likely to respond (58.5%). Families who were mailed the questionnaires in Vietnamese, Korean, or Chinese were equally likely to respond or not respond. There was also a significant association between race/ethnicity and response rate ($\chi^2 = 117.3$, $P < .001$). White families and black/African American families were less likely to respond (45.7% and 36.5% responded, respectively), while Hispanic/Latino families were more likely to respond (53.0%). Asian/Pacific Islanders, American Indian/Native Alaskans, and

those for whom ethnicity was not indicated were equally likely to respond or not respond.

Of the 10 241 participating families with children ages 2–16 years, 10 241 parents completed the parent-proxy report measure and/or the additional survey items. The child self-report measure was completed by 5991 children ages 5–16. For 5991 children ages 5–16 years, both child-self report and parent proxy-report were available. For children ages 5–16 overall, 7021 parents completed enough items on the PedsQL 4.0 to derive at least 1 subscale score and/or summary score (eg, their data were included in the sample sizes in the tables). For these 7021 parents who completed a parent proxy-report for children ages 5–16, 5905 (84.1%) children completed a child self-report with enough items to derive at least 1 subscale score and/or summary score to be included in the data tables. For ages 5–7 only, there were 2472 parent proxy-reports and 2079 (84.1%) child self-reports; for ages 8–12, 3161 parent proxy-reports and 2673 (84.6%) child self-reports; for ages 13–16, 1388 parent proxy-reports and 1153 (83.1%) child-self reports. Thus, across ages 5–16 years, there were approximately the same percentages of child self-reports completed when parent proxy-reports were completed.

The average age of the 5332 boys (52.1%) and 4909 girls (47.9%) was 7.9 years (SD = 4.0) with a range of 2.0–16.4 years. For child self-report, the average age of the 3139 boys (52.4%) and 2852 girls (47.6%) was 9.8 years (SD = 3.15) with a range of 5.0–16.4. The sample was heterogeneous with respect to race/ethnicity, with 1407 (13.7%) white, 6299 (61.5%) Hispanic/Latino, 240 (2.3%) black/African American, 1204 (11.8%) Asian/Pacific Islander, 41 (0.4%) American Indian or Native Alaskan, and 1050 (10.3%) missing values. With respect to socioeconomic status, the sample was representative of new SCHIP enrollees, that is, low-income families (<250% of the federal poverty level).

The sample included 8836 (86.3%) healthy children and 847 (8.3%; missing = 558, 5.4%) children whose parents reported the presence of a chronic health condition. Of the children with a chronic health condition, 364 (43.0%) had asthma, 84 (9.9%) had ADHD, 54 (6.4%) had depression, 10 (1.2%) had diabetes, and 232 (27.4%) had another chronic health condition as reported by their parents, with 103 (12.2%) missing values. We explored the rates of parent-reported chronic health condition by language group. There was an overall significant effect ($\chi^2 = 82.92$, $P < .001$). For families who completed the PedsQL in English, 11.6% reported a chronic health condition; in Spanish, 6.7%; in Vietnamese, 5.0%; in Korean, 11.7%; and in Chinese, 8.6%.

### Feasibility

To assess the feasibility of mail survey administration, the percentage of missing values was calculated. For child self-report and parent-proxy report, the percentage of missing item responses was 1.8% and 2.4%, respectively. However, the overall percentage of missing values on the parent-proxy report for the School Functioning Scale for toddlers (ages 2–4) was 52%, insofar as many children ages 2–4 do not attend school. Further exploration of the School Functioning Subscale data for ages 2–4 revealed an age trend within that group, so that for age 2, the missing subscale data = 67%; for age 3, 55%; and for age 4, 34%. Table 1 shows percentages of missing values by gender, age, language, and race/ethnicity for the Total Score.628 For child self-report, the missing values were comparable across languages except for a higher rate of missing values among Vietnamese. However, there were only 43 Vietnamese respondents, and the largest number of missing values for an individual item was 5. Therefore the larger percentage of missing values may reflect the relatively small Vietnamese sample.

### Descriptive Statistics

Table 2 presents means and SDs of the PedsQL 4.0 scores for child self-report for ages 5–16 and parent proxy-report for ages 2–16 for the total sample. The mean scale scores for the survey sample are generally consistent with the PedsQL 4.0 initial field test in health care settings.[21]

### Internal Consistency Reliability

Internal consistency reliability alpha coefficients by age group are presented in Table 3. The majority of the child self-report scales and parent proxy-report scales exceeded the minimum reliability standard of .70 required for group comparisons, while the Total Scale Score across the ages approached or exceeded the reliability criterion of .90 recommended for analyzing individual patient scale scores. These alpha coefficients are consistent with the PedsQL 4.0 initial field test.[21] The sample sizes listed in Table 3 differ from those of the overall sample. Given that there are differences in sample size for individual subscales (eg, fewer responses on the School Functioning Scale), the PedsQL Total Score reliability coefficients are calculated only for those cases where all items have been completed.

### Minimal Clinically Important Difference

Table 2 also presents the SEM for both child self-report and parent proxy-report. These values suggest, for example, that a 4.4 change in the Total Scale Score for child self-report is a minimal clinically meaningful difference. Likewise, a 4.5 change in the Total Scale Score for parent proxy-report is a minimal clinically meaningful difference.

### Construct Validity

Table 4 contains the PedsQL 4.0 scores for healthy children and children with a chronic health condition within the sample. Consistent with previous research with the PedsQL 4.0,[21–30] healthy children scored significantly higher on the PedsQL 4.0 (better HRQOL) than children with a chronic health condition.

Table 5 contains the PedsQL 4.0 total scores for all children for number of days missed from school, days sick in bed or too ill to play, and days needing someone to care for the child. Consistent with previous PedsQL 4.0

**Table 1.** PedsQL 4.0 Generic Core Total Scale Scores by Gender, Age, Language, and Race/Ethnicity for Child Self-Report and Parent Proxy-Report*

| | Child Self-Report (Total Score) | | | | | | Parent Proxy-Report (Total Score) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Demographics | N | α | Mean | SD | Difference* | % Miss | N | α | Mean | SD | Difference* | % Miss |
| Gender | | | | | | | | | | | | |
| Male | 3128 | 0.89 | 83.16 | 13.06 | | 0.8 | 5236 | 0.92 | 81.25 | 15.90 | | 2.0 |
| Female | 2844 | 0.90 | 82.54 | 13.27 | | 0.5 | 4834 | 0.92 | 81.45 | 15.94 | | 2.0 |
| Age | | | | | | | | | | | | |
| Toddler (2–4)[a] | — | — | — | — | | | 3070 | 0.90 | 87.42 | 12.49 | a > b, c, d | 1.8 |
| Young child (5–7)[b] | 2094 | 0.86 | 81.86 | 12.64 | b < c, d | 0.9 | 2464 | 0.91 | 78.02 | 16.44 | | 1.6 |
| Child (8–12)[c] | 2708 | 0.91 | 83.31 | 13.45 | | 1.0 | 3152 | 0.92 | 78.86 | 16.61 | | 1.9 |
| Adolescent (13–18)[d] | 1170 | 0.91 | 83.65 | 13.30 | | 0.3 | 1384 | 0.92 | 79.45 | 16.40 | | 2.0 |
| Language | | | | | | | | | | | | |
| Spanish[a] | 3133 | 0.89 | 82.12 | 13.25 | a < c, d | 0.5 | 5079 | 0.92 | 79.18 | 17.14 | a < b, c, e | 2.4 |
| English[b] | 2520 | 0.89 | 83.27 | 13.06 | b < c, d | 0.7 | 4363 | 0.92 | 83.48 | 14.20 | | 1.1 |
| Chinese[c] | 184 | 0.92 | 86.71 | 12.49 | | 0.3 | 323 | 0.93 | 83.20 | 13.91 | | 3.5 |
| Korean[d] | 92 | 0.90 | 88.09 | 10.93 | | 1.5 | 168 | 0.92 | 82.86 | 15.85 | | 1.6 |
| Vietnamese[e] | 43 | 0.93 | 86.48 | 13.89 | | 7.9 | 137 | 0.95 | 87.35 | 13.56 | | 5.4 |
| Ethnicity/Race | | | | | | | | | | | | |
| Hispanic/Latino[a] | 3659 | 0.89 | 82.42 | 13.11 | | 0.7 | 6189 | 0.92 | 80.40 | 16.47 | | 2.0 |
| White[b] | 848 | 0.90 | 83.70 | 12.91 | | 0.3 | 1394 | 0.92 | 84.53 | 13.39 | b > a, c, f | 1.1 |
| Asian/Pacific Islander[c] | 673 | 0.91 | 85.22 | 13.02 | c > a, f | 1.0 | 1179 | 0.93 | 82.30 | 15.71 | c > a | 2.1 |
| Black/African-American[d] | 143 | 0.88 | 81.75 | 13.08 | | 0.4 | 239 | 0.91 | 82.88 | 13.61 | | 0.6 |
| American Indian/Native Alaskan[e] | 23 | 0.93 | 77.17 | 19.76 | | 0.0 | 41 | 0.94 | 83.75 | 15.80 | | 0.0 |
| Not reported[f] | 626 | 0.89 | 82.28 | 13.39 | | 0.6 | 1028 | 0.92 | 81.15 | 15.78 | | 2.4 |

*Differences between mean Total Scores are significant at the .05 level after utilizing the Bonferroni correction for the number of contrasts. Significant contrasts are indicated by the letters in the Difference column. α indicates Cronbach alpha; % Miss, percent missing values. For Parent Proxy-Report, missing values do not include the parent of toddler (age 2–4) form due to the number of missing values on that scale (11%).

findings,[21] children who missed more days from school, were more often sick in bed and too ill to play, and more often needed someone to care for them demonstrated lower PedsQL 4.0 scores. Children with a chronic health condition were also more likely than healthy children to have missed 4 or more school days in the past 30 days (21%, mean = 2.60, vs 4.5%, mean = 0.71; $t = 18.89$, $P < .001$), have spent 4 or more days sick in bed or too ill to play in the previous month (17%, mean = 1.99 days, vs 4%, mean = 0.66 days; $t = 15.68$, $P < .001$), and to

**Table 2.** Scale Descriptives for PedsQL 4.0 Generic Core Scales: Child Self-Report and Parent Proxy-Report

| | Scale Descriptives | | | | | Minimal Clinically Important Difference |
|---|---|---|---|---|---|---|
| Scale | Number of items | N | Mean | SD | Range | SEM* |
| Child self-report | | | | | | |
| Total Score | 23 | 5972 | 82.87 | 13.16 | 0–100 | 4.36 |
| Physical Health | 8 | 5962 | 86.86 | 13.88 | 0–100 | 6.66 |
| Psychosocial Health | 15 | 5963 | 80.73 | 14.70 | 0–100 | 5.30 |
| Emotional Functioning | 5 | 5961 | 78.21 | 18.64 | 0–100 | 8.94 |
| Social Functioning | 5 | 5948 | 84.04 | 17.43 | 0–100 | 8.36 |
| School Functioning | 5 | 5908 | 79.92 | 16.93 | 0–100 | 9.12 |
| Parent proxy-report | | | | | | |
| Total Score | 23 | 10 070 | 81.34 | 15.92 | 0–100 | 4.50 |
| Physical Health | 8 | 10 050 | 83.26 | 19.98 | 0–100 | 6.92 |
| Psychosocial Health | 15 | 10 071 | 80.22 | 15.84 | 0–100 | 5.49 |
| Emotional Functioning | 5 | 10 044 | 80.28 | 16.99 | 0–100 | 7.79 |
| Social Functioning | 5 | 10 036 | 82.15 | 20.08 | 0–100 | 8.98 |
| School Functioning | 5 | 8466 | 76.91 | 20.16 | 0–100 | 9.67 |

*SEM indicates Standard Error of Measurement and was derived by multiplying the standard deviation by the square root of 1-alpha (Cronbach alpha reliability coefficient). The PedsQL 4.0 scores in the column represent the transformed value of 1 SEM. For example, a change in PedsQL 4.0 Total Scale Score for child self-report of 4.36 represents a minimal clinically important difference.

**Table 3.** PedsQL 4.0 Generic Core Scales Internal Consistency Reliability for Child Self-Report and Parent Proxy-Report by Age and Summary Score/Subscale*

| Scale | Age group | | | | Total Sample |
|---|---|---|---|---|---|
| | Toddler (2–4 years) | Young Child (5–7 years) | Child (8–12 years) | Adolescent (13–18 years) | |
| Child self-report | | N = 2030 | N = 2674 | N = 1159 | |
| Total Score | NA | 0.86 | 0.91 | 0.91 | 0.89 |
| Physical Health | NA | 0.68 | 0.82 | 0.83 | 0.77 |
| Psychosocial Health | NA | 0.83 | 0.88 | 0.89 | 0.87 |
| Emotional Functioning | NA | 0.71 | 0.80 | 0.81 | 0.77 |
| Social Functioning | NA | 0.71 | 0.80 | 0.82 | 0.77 |
| School Functioning | NA | 0.61 | 0.75 | 0.79 | 0.71 |
| Parent proxy-report | N = 3037 | N = 2386 | N = 3108 | N = 1362 | |
| Total Score | 0.89 | 0.91 | 0.92 | 0.92 | 0.92 |
| Physical Health | 0.86 | 0.87 | 0.88 | 0.88 | 0.88 |
| Psychosocial Health | 0.81 | 0.87 | 0.88 | 0.89 | 0.88 |
| Emotional Functioning | 0.75 | 0.79 | 0.81 | 0.83 | 0.81 |
| Social Functioning | 0.77 | 0.77 | 0.79 | 0.80 | 0.79 |
| School Functioning | 0.58 | 0.72 | 0.74 | 0.77 | 0.74 |

*Reliabilities for parent proxy-report of toddlers (ages 2–4 years) Total Score and Psychosocial Health do not include the items in the School Functioning Subscale due to the large number of missing values for this subscale (as toddlers do not all attend school). The Cronbach alpha reported for parents of toddler School Functioning Subscale is based on only 1477 respondents. The alpha values for the Total Sample do not include the parent of toddler form.

have needed someone to care for them on 4 or more days in the previous 30 days (20%, mean = 2.75 days, vs 3.3%, mean = 0.46 days; $t = 20.46$, $P < .001$).

### Health Care Access

Tables 6 and 7 demonstrate that, for child self-report and parent proxy-report scores, families experiencing problems getting care for their children and not receiving care when perceived as necessary had lower scores (worse HRQOL), on average, than those without problems getting care and receiving care when perceived as necessary. In addition, parents of children with a chronic health condition reported greater problems getting care when needed (38%) than parents of healthy children (19%; $\chi^2 = 161.2$, $P < .001$), and not receiving care when needed (31%) as compared with parents of healthy children (16%; $\chi^2 = 117.4$, $P < .001$).

The multivariate linear regressions indicated that problems getting care significantly accounted for 3% of the variance in the Total Scale Score for child self-report ($F_{4,5410} = 116.09$, $P < .001$) and 2% of the variance in parent proxy-report ($F_{4,9210} = 116.29$, $P < .001$) after controlling for chronic health condition status, race/ethnicity, and language. Instances of foregone care also significantly accounted for 3% of the variance in the Total Scale Score for child self-report ($F_{4,5569} = 119.24$, $P < .001$) and for 2% of the variance in parent proxy-report ($F_{4,9419} = 119.96$, $P < .001$) after controlling for chronic health condition status, race/ethnicity, and language.

### PedsQL 4.0 Scores by Gender, Age, Language, and Race/Ethnicity

Table 1 shows the differences in PedsQL 4.0 scores by gender, age, language, and race/ethnicity for child self-report and parent proxy-report. There were no gender differences for either report. For child self-report, younger children ages 5–7 reported lower scores than older children and adolescents by less than 2 points. For parent proxy-report, parents reported significantly higher scores for children ages 2–4. In terms of language, English-speaking and Spanish-speaking children self-reported comparable PedsQL scores, whereas Chinese-speaking and Korean-speaking children self-reported higher scores than English-speaking and Spanish-speaking children. For parent proxy-report, Spanish-speaking parents reported lower child scores than English-speaking, Chinese-speaking, and Vietnamese-speaking parents. In terms of race/ethnicity, children from Asian/Pacific Islander backgrounds self-reported higher PedsQL scores than Hispanic/Latino children. For parent proxy-report, parents from Asian/Pacific Islander backgrounds reported higher scores than parents from Hispanic/Latino backgrounds; white parents reported higher scores than Hispanic/Latino and Asian/Pacific Islander parents. The differences in most cases were relatively small in absolute value, but reach statistical significance in part as a result of the large sample size.

### PedsQL 4.0 Cut-Off Point Scores

Table 8 shows the PedsQL 4.0 cut-off point scores for both child self-report and parent proxy-report. One standard deviation below the population mean was explored as a meaningful cut-off point score for an at-risk status for impaired HRQOL relative to the population sample. For child self-report, the PedsQL 4.0 Total Scale Score cut-off point score was 69.7 (parent proxy-report score of 65.4). In order to provide the context for these cut-off scores, it is useful to examine PedsQL 4.0 Total Scale Scores for children with physician-diagnosed chronic health conditions. For example, children with newly diagnosed cancer on treatment self-report a PedsQL 4.0 Total Scale Score of 68.9 (parent proxy-report score of

**Table 4.** Scale Descriptives for the PedsQL 4.0 Generic Core Scales Child Self-Report and Parent Proxy-Report: Healthy Sample and Chronic Health Condition Sample

| Scale | Healthy Sample | | | Chronic Health Condition† | | | Difference | Effect Size‡ | *t* Score | *P* Value* |
|---|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | | | | |
| Child self-report | | | | | | | | | | |
| Total Score | 5079 | 83.91 | 12.47 | 574 | 74.16 | 15.38 | 9.75 | 0.78 | −17.29 | .001 |
| Physical Health | 5070 | 87.77 | 13.12 | 574 | 79.47 | 17.07 | 8.30 | 0.63 | −13.89 | .001 |
| Psychosocial Health | 5070 | 81.83 | 13.97 | 573 | 71.32 | 17.13 | 10.51 | 0.75 | −16.65 | .001 |
| Emotional Functioning | 5068 | 79.21 | 18.02 | 573 | 69.32 | 21.36 | 9.89 | 0.55 | −12.21 | .001 |
| Social Functioning | 5056 | 84.97 | 16.71 | 572 | 76.36 | 21.57 | 8.61 | 0.52 | −11.30 | .001 |
| School Functioning | 5026 | 81.31 | 16.09 | 568 | 68.27 | 19.05 | 13.04 | 0.81 | −17.95 | .001 |
| Parent proxy-report | | | | | | | | | | |
| Total Score | 8713 | 82.29 | 15.55 | 831 | 73.14 | 16.46 | 9.15 | 0.59 | −16.13 | .001 |
| Physical Health | 8696 | 84.08 | 19.70 | 830 | 76.99 | 20.20 | 7.09 | 0.36 | −9.89 | .001 |
| Psychosocial Health | 8714 | 81.24 | 15.34 | 830 | 71.04 | 17.32 | 10.20 | 0.66 | −18.09 | .001 |
| Emotional Functioning | 8692 | 81.20 | 16.40 | 829 | 71.08 | 19.75 | 10.12 | 0.62 | −16.65 | .001 |
| Social Functioning | 8690 | 83.05 | 19.66 | 824 | 75.06 | 21.75 | 7.99 | 0.41 | −11.04 | .001 |
| School Functioning | 7287 | 78.27 | 19.64 | 756 | 65.58 | 20.75 | 12.69 | 0.65 | −16.82 | .001 |

*$P$ value = statistical significance.

†Children with a chronic health condition were identified by their parents as having 1 of the following conditions: asthma, diabetes, attention deficit hyperactivity disorder (ADHD), depression, or ''other.''

‡Effect sizes are designated as small (.20), medium (.50), and large (.80).

67.0).[23] Similarly, children with rheumatic conditions (eg, juvenile rheumatoid arthritis) self-report a PedsQL 4.0 Total Scale Score of 72.1 (parent proxy-report score of 71.0).[22] Thus, scores approximating 1 SD below the population sample mean represent Total Scale Scores similar to children with a severe chronic health condition.

### Parent/Child Concordance

Table 9 shows the intercorrelations between child self-report and parent proxy-report across the ages 5–16. The overall scale intercorrelations are generally consistent with other PedsQL 4.0 studies.[21–23,25,27,30] Although parent/child concordance has not typically been reported for children younger than 7 years of age for HRQOL instruments,[31] the trend toward higher intercorrelations with increasing age in the extant pediatric HRQOL literature is undeterminable given the small number of studies and inconsistent findings reported.[31] The trend toward higher intercorrelations with increasing age in the present study is perhaps consonant with the trend toward higher scale reliabilities with increasing age for self-report (Table 3). Lower scale reliabilities indicate greater measurement error, which may attenuate the intercorrelations between self and proxy reporters. An additional explanation may be the greater verbal communication skills typically manifested with increasing developmental age.

## DISCUSSION

This study presents the measurement properties for the PedsQL 4.0 Generic Core Scales as a population health measure. The analyses support the feasibility, reliability, and validity of the PedsQL 4.0 as a child self-report and parent proxy-report HRQOL measurement instrument for pediatric population health. The PedsQL 4.0 is the only empirically validated generic pediatric HRQOL measurement instrument of which we are aware to span this broad age range for child self-report and parent proxy-report while maintaining item and scale construct consistency.[6,7,31,32] A distinct advantage of the Generic Core Scales is the large and growing database of healthy children and children with chronic health conditions that provides the

**Table 5.** PedsQL Total Scores for Number of Days Missed from School, Days Needing Someone to Care for the Child, and Days Sick in Bed or Too Ill to Play for Child Self-Report and Parent Proxy-Report*

| | Days Missed From School | | | Days Needed Care | | | Days Sick in Bed/Too Ill to Play | | |
|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | N | Mean | SD |
| Child self-report | | | | | | | | | |
| 0 days | 2558 | 84.62 | 12.41 | 2974 | 83.96 | 12.64 | 2756 | 84.23 | 12.50 |
| 1–3 days | 1129 | 78.80 | 13.52 | 538 | 77.46 | 13.53 | 932 | 78.34 | 13.64 |
| >3 days | 254 | 73.44 | 15.40 | 161 | 72.48 | 15.38 | 181 | 73.71 | 16.13 |
| Parent proxy-report | | | | | | | | | |
| 0 days | 4042 | 82.80 | 15.25 | 4717 | 82.17 | 15.50 | 4371 | 82.53 | 15.40 |
| 1–3 days | 1555 | 76.71 | 15.82 | 861 | 77.74 | 14.91 | 1548 | 77.62 | 15.55 |
| >3 days | 382 | 71.14 | 16.58 | 287 | 73.20 | 15.96 | 339 | 73.83 | 16.70 |

*All ANOVAs are significant at $P < .001$. All Tukey post hoc analyses between groups are significant at $P < .001$.

**Table 6.** Scale Descriptives of PedsQL 4.0 Generic Core Scales Child Self-Report and Parent Proxy-Report: Problems Getting Necessary Care for the Child

| Scale | No Problems | | | Yes Problems | | | Difference | Effect Size† | *t* Score | *P* Value* |
|---|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | | | | |
| Child self-report | | | | | | | | | | |
| Total Score | 4524 | 84.12 | 12.57 | 1192 | 77.72 | 14.19 | 6.40 | 0.51 | −15.20 | .001 |
| Physical Health | 4515 | 88.04 | 13.16 | 1191 | 82.17 | 15.43 | 5.87 | 0.45 | −13.18 | .001 |
| Psychosocial Health | 4518 | 82.02 | 14.12 | 1189 | 75.32 | 15.77 | 6.70 | 0.47 | −14.20 | .001 |
| Emotional Functioning | 4516 | 79.51 | 18.22 | 1189 | 72.81 | 19.44 | 6.70 | 0.37 | −11.12 | .001 |
| Social Functioning | 4508 | 85.27 | 16.62 | 1185 | 78.84 | 19.58 | 6.43 | 0.39 | −11.40 | .001 |
| School Functioning | 4477 | 81.27 | 16.36 | 1180 | 74.31 | 18.09 | 6.96 | 0.43 | −12.72 | .001 |
| Parent proxy-report | | | | | | | | | | |
| Total Score | 7667 | 82.64 | 15.47 | 2045 | 76.62 | 16.46 | 6.02 | 0.39 | −15.43 | .001 |
| Physical Health | 7650 | 84.43 | 19.61 | 2042 | 79.05 | 20.51 | 5.38 | 0.27 | −10.90 | .001 |
| Psychosocial Health | 7671 | 81.59 | 15.30 | 2044 | 75.22 | 16.59 | 6.37 | 0.42 | −16.43 | .001 |
| Emotional Functioning | 7648 | 81.59 | 16.37 | 2039 | 75.05 | 18.09 | 6.54 | 0.40 | −15.67 | .001 |
| Social Functioning | 7647 | 83.48 | 19.63 | 2036 | 77.53 | 20.78 | 5.95 | 0.30 | −12.01 | .001 |
| School Functioning | 6405 | 78.38 | 19.63 | 1751 | 71.74 | 21.01 | 6.64 | 0.34 | −12.35 | .001 |

*$P$ value = statistical significance.
†Effect sizes are designated as small (.20), medium (.50), and large (.80).

opportunity to benchmark HRQOL for specific pediatric populations.[21–30]

Items on the PedsQL 4.0 had minimal missing responses, suggesting that children and parents are willing and able to provide good-quality data regarding the child's HRQOL. The self-report and proxy-report internal consistency reliabilities generally exceeded the recommended minimum alpha coefficient standard of .70 for group comparisons. Across the ages, the Generic Core Scales Total Score for both child self-report and parent proxy-report approached or exceeded an alpha of .90, recommended for individual patient analysis,[46] making the Total Scale Score suitable as a summary score for the primary analysis of HRQOL outcome in population health analyses. The Physical Health and Psychosocial Health Summary Scores are recommended for secondary analyses. The Emotional, Social, and School Functioning Subscales may be utilized to examine specific domains of functioning, with the caveat that, until further testing is conducted, the School Functioning Subscales should be used only for descriptive or exploratory analyses for parent proxy-report for ages 2–4 and child self-report for ages 5–7. Although Cronbach's alpha internal consistency coefficients represent the lower bound of the actual reliability of a measurement instrument and thus are a conservative estimate of actual reliability,[58] until further testing is conducted, scales that do not achieve the standard of .70 should be used only for descriptive or exploratory analyses. Additionally, the large number of missing values for the School Functioning Subscale for ages 2–4 suggest that this scale for these ages should only be used for descriptive purposes, given that a substantial number of children do not attend school during ages 2–4.

The Generic Core Scales performed as hypothesized utilizing the known-groups method. The PedsQL 4.0 differentiated HRQOL in healthy children as a group in com-

**Table 7.** Scale Descriptives of PedsQL 4.0 Generic Core Scales Child Self-Report and Parent Proxy-Report: Thought the Child Should Get Medical Care But Did Not Get It

| Scale | Got Medical Care | | | Did Not Get Medical Care | | | Difference | Effect Size† | *t* Score | *P* Value* |
|---|---|---|---|---|---|---|---|---|---|---|
| | N | Mean | SD | N | Mean | SD | | | | |
| Child self-report | | | | | | | | | | |
| Total Score | 4740 | 84.13 | 12.57 | 1143 | 77.63 | 14.25 | 6.50 | 0.52 | −15.30 | .001 |
| Physical Health | 4732 | 87.98 | 13.14 | 1142 | 82.25 | 15.71 | 5.73 | 0.44 | −12.70 | .001 |
| Psychosocial Health | 4732 | 82.08 | 14.19 | 1141 | 75.11 | 15.74 | 6.97 | 0.49 | −14.63 | .001 |
| Emotional Functioning | 4730 | 79.70 | 18.10 | 1142 | 72.11 | 19.55 | 7.59 | 0.42 | −12.52 | .001 |
| Social Functioning | 4723 | 85.21 | 16.77 | 1136 | 79.00 | 19.33 | 6.21 | 0.37 | −10.87 | .001 |
| School Functioning | 4687 | 81.30 | 16.33 | 1133 | 74.30 | 18.14 | 7.00 | 0.43 | −12.66 | .001 |
| Parent proxy-report | | | | | | | | | | |
| Total Score | 8147 | 82.56 | 15.46 | 1784 | 76.06 | 16.68 | 6.50 | 0.42 | −15.87 | .001 |
| Physical Health | 8126 | 84.34 | 19.59 | 1785 | 78.59 | 20.90 | 5.75 | 0.29 | −11.09 | .001 |
| Psychosocial Health | 8147 | 81.52 | 15.31 | 1785 | 74.58 | 16.74 | 6.94 | 0.45 | −17.06 | .001 |
| Emotional Functioning | 8123 | 81.63 | 16.29 | 1781 | 74.12 | 18.54 | 7.51 | 0.46 | −17.18 | .001 |
| Social Functioning | 8120 | 83.40 | 19.56 | 1779 | 76.98 | 21.25 | 6.42 | 0.33 | −12.35 | .001 |
| School Functioning | 6797 | 78.20 | 19.80 | 1556 | 71.52 | 20.62 | 6.68 | 0.34 | −11.93 | .001 |

*$P$ value = statistical significance.
†Effect sizes are designated as small (.20), medium (.50), and large (.80).

**Table 8.** PedsQL 4.0 Generic Cores Scales Cut-Off Scores for Child Self-Report and Parent Proxy-Report

| | | | | >1 SD* | | |
|---|---|---|---|---|---|---|
| Scale | N | Mean | SD | Score | N | % |
| Child self-report | | | | | | |
| Total Score | 5972 | 82.87 | 13.16 | 69.71 | 1010 | 17 |
| Physical Health | 5962 | 86.86 | 13.88 | 72.98 | 881 | 15 |
| Psychosocial Health | 5963 | 80.73 | 14.70 | 66.03 | 941 | 16 |
| Emotional Functioning | 5961 | 78.21 | 18.64 | 59.57 | 847 | 14 |
| Social Functioning | 5948 | 84.04 | 17.43 | 66.61 | 946 | 16 |
| School Functioning | 5908 | 79.92 | 16.93 | 62.99 | 1002 | 17 |
| Parent proxy-report | | | | | | |
| Total Score | 10 070 | 81.34 | 15.92 | 65.42 | 1840 | 18 |
| Physical Health | 10 050 | 83.26 | 19.98 | 63.28 | 1722 | 17 |
| Psychosocial Health | 10 071 | 80.22 | 15.84 | 64.38 | 1802 | 18 |
| Emotional Functioning | 10 044 | 80.28 | 16.99 | 63.29 | 1590 | 16 |
| Social Functioning | 10 036 | 82.15 | 20.08 | 62.07 | 1897 | 19 |
| School Functioning | 8466 | 76.91 | 20.16 | 56.75 | 1625 | 19 |

*>1 SD (standard deviation) demonstrates the scores that fall 1 SD below the population sample mean and represent an at-risk status for impaired health-related quality of life. Twenty-one percent (N = 213; 21%) of children whose Total Score fell more than 1 SD below the mean had a chronic health condition, as indicated by their parents.

parison with children with chronic health conditions as a group. The PedsQL 4.0 was also associated with measures of health care access, number of days missed from school, days sick in bed or too ill to play, and days needing someone to care for the child.

The cross-informant variance observed in the parent/child intercorrelations matrix supports the need to measure the perspectives of child and parent informants in evaluating HRQOL in pediatric population health. The availability of a validated parent proxy-report measure in pediatric population health provides the opportunity to estimate child HRQOL when the child is either unable or unwilling to complete the HRQOL measure, or as proxy information when young child self-report scale reliabilities do not achieve the .70 standard. Although the intercorrelations between child and parent report across the physical, emotional, social, and school domains might be expected to follow the conceptualization that more observable domains (ie, physical functioning) would yield higher intercorrelations, this has not necessarily been the case in either PedsQL publications across various pediatric chronic health conditions or the published literature using other HRQOL instruments. In a comprehensive review, Eiser and Morse[31] found mixed results in terms of higher intercorrelations between self and proxy report of physical functioning across pediatric HRQOL instruments, with most studies demonstrating this effect while some did not. For previous PedsQL 4.0 publications, we have generally found higher self and proxy report intercorrelations for physical functioning in comparison with the other domains, although these differences have not been large,[21,23,27] except for children with arthritis and other rheumatologic conditions in which physical functioning is a salient concern.[22] For children with diabetes, in which physical functioning is not as salient a concern, the intercorrelation between self and proxy report on the Physical Functioning Scale was not the highest intercorrelation.[25] Thus, the findings across PedsQL studies appear consistent with the extant pediatric HRQOL literature across different instruments in regard to the effect sizes of the intercorrelations between the physical functioning and other relevant HRQOL domains.[31]

**Table 9.** Pearson Correlation Coefficients Between PedsQL 4.0 Generic Core Scales for Parent Proxy-Report and Child Self-Report Across Ages 5–18 Years*

| | Age Group (years) | | | |
|---|---|---|---|---|
| Scale | 5–7 | 8–12 | 13–18 | Total Sample |
| Total Score | 0.52 | 0.66 | 0.68 | 0.61 |
| Physical Health | 0.34 | 0.49 | 0.51 | 0.44 |
| Psychosocial Health | 0.59 | 0.71 | 0.75 | 0.68 |
| Emotional Functioning | 0.70 | 0.77 | 0.79 | 0.75 |
| Social Functioning | 0.45 | 0.61 | 0.63 | 0.56 |
| School Functioning | 0.50 | 0.62 | 0.68 | 0.59 |

*All correlations are significant at the $P < .01$ level (2-tailed). Effect sizes are designated as small (.10), medium (.30), and large (.50).

The findings in the comparisons between scores of healthy children and children with chronic health conditions warrant further discussion. Consistent with the overall extant literature on the adaptation of children with chronic health conditions,[59] children with chronic health conditions not only were reported to experience lower physical functioning, but also manifested lower emotional, social, and school functioning in comparison with healthy children. School functioning was most impacted by chronic health conditions; this is often considered a reflection of the higher rates of school absences for children with chronic health conditions in comparison with healthy children.[59] The lower PedsQL 4.0 scores for children with chronic health conditions on the Emotional Functioning Scale may reflect in part that the chronic health condition definition utilized in the present study included both physical and mental health conditions, as well as the documented psychological and social at-risk status for children with chronic health conditions reported in the literature.[60]

These findings with the PedsQL 4.0 have potential implications for SCHIP. Nearly 5 million children in the United States, 7.3% of the pediatric population, experience at least one unmet health care need, with near-poor and poor children approximately 3 times more likely to have an unmet health care need.[61] Children without health insurance are also approximately 3 times more likely to have an unmet health care need. Two thirds of the children with an unmet health care need live in low-income families.[61] SCHIP was created as Title XXI of the Social Security Act through legislation enacted in the 1997 Balanced Budget Act. The SCHIP is the largest expansion of expenditures for child health care since Medicaid. The challenges for the states are to identify and enroll eligible children from low-income families and to assure that these children receive quality comprehensive health care services. Additionally, SCHIP has previously been required to include an evaluation component. Although a major challenge for SCHIP has been to document and implement a successful strategy for enrolling eligible children,[33] measuring the number of children enrolled is a necessary but not sufficient outcome-measurement strategy. If states measure the number of children enrolled in SCHIP without simultaneously measuring the use and effectiveness of health care,[62] including children's health outcomes, they will be uninformed of the potential impact of health insurance on access and on the health and well-being of the children served. Further, measuring the health care access and health outcomes of children enrolled in SCHIP provides the opportunity to evaluate the relative benefits of different insurance plans and intervention strategies to overcome barriers to health care access and improve the health of the children in these statewide programs. The findings from this cross-sectional investigation suggest that parents' reports of problems accessing health care for their children when it is perceived as necessary is associated with child and parent perceptions of worse health-related quality of life.

The present findings have several potential limitations. While a 51% response rate was expected for the mode and method of survey administration utilized (one-time only mailing),[57] a higher response rate would be achievable with more contacts (eg, a second mailing, postcard reminders, telephone follow-up call).[57] However, the limited funding available for this statewide program evaluation during year 1 did not provide the resources for multiple contacts. The year 2 evaluation received resources to conduct multiple contacts. Following standard survey research methodology,[57] a reminder postcard was mailed after the initial mail survey, with nonrespondents receiving a second mail survey. Nonrespondents to the second mail survey received a telephone follow-up call. Of the 10 241 families surveyed during year 1, 6881 (67.2%) were still enrolled in SCHIP at year 2. Of those families still enrolled, 87.3% (n = 6005) returned a completed PedsQL 4.0 year 2 survey. This suggests that it is important to distinguish between the feasibility of a measurement instrument versus the achievable response rate indigenous to a particular survey research methodology.

A prospective analysis will be needed to confirm a causal association between health care access and HRQOL. Parents reported on their children's chronic health condition information. Objective measures of chronic health condition would strengthen the validation process. However, in previous PedsQL 4.0 clinical research in pediatric patients with cancer, cardiac, or rheumatic chronic health conditions, objective medical diagnosis of these chronic diseases demonstrated similar differences between healthy children and children with chronic health conditions as shown in the present findings.[22–24] Last, although the Spanish language translation of the PedsQL 4.0 had been previously validated in the PedsQL 4.0 field test,[21] the Vietnamese, Korean, and Chinese translations had not been previously validated. However, the Vietnamese, Korean, and Chinese translations were conducted by EDS using forward/backward translation methodology. This translation methodology has been successfully utilized in other PedsQL 4.0 international language translations, including German[28] and Dutch[29] translations. Nevertheless, it is recommended that the Vietnamese, Korean, and Chinese translations undergo further field testing.

In conclusion, these PedsQL 4.0 findings demonstrate the feasibility and measurement properties required for community and general population health survey research and evaluation. Measuring perceived health from the perspective of children and their parents provides a level of accountability consistent with the Institute of Medicine report on the quality of care in America. Additionally, population-wide monitoring has been recommended for addressing socioeconomic, racial, and ethnic disparities in health care quality.[63] As the consumers of pediatric health care, children and parents are uniquely positioned to give their perspectives on health care quality through their perceptions of child health-related quality of life outcomes.

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## REFERENCES

1. Fayers PM, Machin D. *Quality of Life: Assessment, Analysis, and Interpretation.* New York, NY: Wiley; 2000.
2. Spilker B. *Quality of Life and Pharmacoeconomics in Clinical Trials.* Philadelphia, Pa: Lippincott-Raven; 1996.
3. Varni JW, Seid M, Kurtin PS. Pediatric health-related quality of life measurement technology: a guide for health care decision makers. *J Clin Outcomes Manag.* 1999;6:33–40.
4. Smith KW, Avis NE, Assmann SF. Distinguishing between quality of life and health status in quality of life research: a meta-analysis. *Qual Life Res.* 1999;8:447–459.
5. World Health Organization. *Constitution of the World Health Organization Basic Document.* Geneva, Switzerland: World Health Organization; 1948.
6. Drotar D., ed. *Measuring Health-Related Quality of Life in Children and Adolescents.* Mahwah, NJ: Erlbaum; 1998.
7. Koot HM, Wallander JL, eds. *Quality of Life in Child and Adolescent Illness: Concepts, Methods and Findings.* East Sussex, UK: Brunner-Routledge; 2001.
8. Lewin-Epstein N, Sagiv-Schifter T, Shabtai EL, Shmueli A. Validation of the 36-item Short-Form Health Survey (Hebrew ver-

sion) in the adult population of Israel. *Med Care.* 1998;36: 1361–1370.
9. Burdine JN, Felix MRJ, Abel AL, et al. The SF-12 as a population health measure: an exploratory examination of potential for application. *Health Serv Res.* 2000;35:885–904.
10. Au DH, McDonell MB, Martin DC, Fihn SD. Regional variations in health status. *Med Care.* 2001;39:879–888.
11. Sullivan M, Karlsson J. The Swedish SF-36 Health Survey III. Evaluation of criterion-based validity: results from normative population. *J Clin Epidemiol.* 1998;51:1105–1113.
12. Centers for Disease Control and Prevention. *Measuring Healthy Days: Population Assessment of Health-Related Quality of Life.* Atlanta, Ga: CDC; 2000.
13. McGlynn EA, Halfon N. Overview of issues in improving quality of care for children. *Health Serv Res.* 1998;33:977–1000.
14. Newacheck PW, Taylor WR. Childhood chronic illness: prevalence, severity, and impact. *Am J Public Health.* 1992;82:364–371.
15. McCowan C, Bryce FP, Neville RG, et al. School absence: a valid morbidity marker for asthma? *Health Bull.* 1996;54:307–313.
16. Weitzman M. School absence rates as outcome measures in studies of children with chronic illness. *J Chronic Dis.* 1986; 39:799–808.
17. Forrest CB, Simpson L, Clancy C. Child health services research: challenges and opportunities. *JAMA.* 1997;277:1787–1793.
18. Forrest CB, Shipman SA, Dougherty D, Miller MR. Outcomes research in pediatric settings: recent trends and future directions. *Pediatrics.* 2003;111:171–178.
19. Kaplan RM. Quality of life in children: a health care policy perspective. In: Koot HM, Wallander JL, eds. *Quality of Life in Child and Adolescent Illness: Concepts, Methods, and Findings.* East Sussex, UK: Brunner-Routledge; 2001:89–120.
20. Varni JW, Seid M, Rode CA. The PedsQL™: measurement model for the Pediatric Quality of Life Inventory. *Med Care.* 1999; 37:126–139.
21. Varni JW, Seid M, Kurtin PS. The PedsQL™ 4.0: reliability and validity of the Pediatric Quality of Life Inventory™ Version 4.0 Generic Core Scales in healthy and patient populations. *Med Care.* 2001;39:800–812.
22. Varni JW, Seid M, Knight TS, et al. The PedsQL™ in pediatric rheumatology: reliability, validity, and responsiveness of the Pediatric Quality of Life Inventory™ Generic Core Scales and Rheumatology Module. *Arthritis Rheum.* 2002;46:714–725.
23. Varni JW, Burwinkle TM, Katz ER, et al. The PedsQL™ in pediatric cancer: reliability and validity of the Pediatric Quality of Life Inventory™ Generic Core Scales, Multidimensional Fatigue Scale, and Cancer Module. *Cancer.* 2002;94:2090–2106.
24. Varni JW, Seid M, Knight TS, et al. The PedsQL™ 4.0 Generic Core Scales: sensitivity, responsiveness, and impact on clinical decision-making. *J Behav Med.* 2002;25:175–193.
25. Varni JW, Burwinkle TM, Jacobs JR, et al. The PedsQL™ in Type 1 and Type 2 diabetes: reliability and validity of the Pediatric Quality of Life Inventory™ Generic Core Scales and Type 1 Diabetes Module. *Diabetes Care.* 2003;26:631–637.
26. Schwimmer JB, Burwinkle TM, Varni JW. Health-related quality of life of severely obese children and adolescents. *JAMA.* 2003;289:1813–1819.
27. Uzark K, Jones K, Burwinkle TM, Varni JW. The Pediatric Quality of Life Inventory™ in children with heart disease. *Prog Pediatr Cardiol.* In press.
28. Felder-Puig R, Frey E, Proksch K, et al. Validation of the German version of the Pediatric Quality of Life Inventory™ (PedsQL™) in childhood cancer patients off treatment and children with epilepsy. *Qual Life Res.* In press.
29. Bastiaansen D, Koot HM, Bongers IL, et al. Measuring quality of life in children referred for psychiatric problems: psychometric properties of the Dutch version of the PedsQL™ 4.0 Generic Core Scales. *Qual Life Res.* In press.
30. Powers SW, Patton SR, Hommel KA, Hershey AD. Quality of life in childhood migraines: clinical impact and comparison to other chronic illnesses. *Pediatrics.* 2003;112:e1–e5.
31. Eiser C, Morse R. Quality of life measures in chronic diseases of childhood. *Health Tech Assess.* 2001;5:1–158.
32. Eiser C, Morse R. A review of measures of quality of life for children with chronic illness. *Arch Dis Child.* 2001;84:205–211.
33. Halfon N, Inkelas M, Newacheck PW. Enrollment in the State Child Health Insurance Program: A conceptual framework for evaluation and continuous quality improvement. *Milbank Q* 1999;77:181–204.
34. Ware JE, Bayliss MS, Rogers WH, et al. Differences in 4-year health outcomes for elderly and poor, chronically ill patients treated in HMO and fee-for-service systems. *JAMA.* 1996;276.
35. Varni JW, Thompson KL, Hanson V. The Varni/Thompson Pediatric Pain Questionnaire: I. Chronic musculoskeletal pain in juvenile rheumatoid arthritis. *Pain.* 1987;28:27–38.
36. Varni JW, Waldron SA, Gragg RA, et al. Development of the Waldron/Varni Pediatric Pain Coping Inventory. *Pain.* 1996;67: 141–150.
37. Thompson KL, Varni JW. A developmental cognitive-biobehavioral approach to pediatric pain assessment. *Pain.* 1986;25:282–296.
38. Fairclough DL. *Design and Analysis of Quality of Life Studies in Clinical Trials: Interdisciplinary Statistics.* New York: Chapman & Hall/CRC; 2002.
39. Ware JE. *SF-36 Health Survey: Manual and Interpretation Guide.* Boston, Mass: The Health Institute; 1993.
40. Fairclough DL, Cella DF. Functional Assessment of Cancer Therapy (FACT-G): Non-Response to Individual Questions. *Qual Life Res.* 1996;5:321–329.
41. Seid M, Varni JW, Bermudez LO, et al. Parent's perceptions of primary care: measuring parent's experiences of pediatric primary care quality. *Pediatrics.* 2001;108:264–270.
42. Hays RD, Shaul JA, Williams VSL, et al. Psychometric properties of the CAHPS 1.0 survey measures. *Med Care.* 1999;37: MS22–MS31.
43. Essink-Bot ML, Krabbe PFM, Bonsel GJ, Aaronson NK. An empirical comparison of four generic health status measures: the Nottingham Health Profile, the Medical Outcomes Study 36-Item Short-Form Health Survey, the COOP/WONCA Charts, and The EuroQol Instrument. *Med Care.* 1997;35:522–537.
44. McHorney CA, Ware JE, Lu JFR, Sherbourne CD. The MOS 36-Item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. *Med Care.* 1994;32:40–66.
45. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika.* 1951;16:297–334.
46. Nunnally JC, Bernstein IR. *Psychometric Theory.* 3rd ed. New York, NY: McGraw-Hill; 1994.
47. Pedhazur EJ, Schmelkin LP. *Measurement, Design, and Analysis: An Integrated Approach.* Hillsdale, NJ: Erlbaum; 1991.
48. McHorney CA, Ware JE, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care.* 1993;31:247–263.
49. McHorney CA, Ware JE, Rogers W, et al. The validity and relative precision of MOS short- and long-form health status scales and Dartmouth COOP charts: results from the Medical Outcomes Study. *Med Care.* 1992;30:MS253–MS265.
50. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* 2nd ed. Hillsdale, NJ: Erlbaum; 1988.
51. Wyrwich K, Tierney W, Wolinsky F. Further evidence supporting an SEM-based criterion for identifying meaningful intra-individual changes in health-related quality of life. *J Clin Epidemiol.* 1999;52:861–873.
52. Jaeschke R, Singer J, Guyatt GH. Measurement of health status: Ascertaining the minimal clinically important difference. *Controlled Clin Trials* 1989;10:407–415.
53. Wyrwich K, Tierney W, Wolinsky F. Using the standard error

of measurement to identify important changes on the Asthma Quality of Life Questionnaire. *Qual Life Res.* 2002;11:1–7.
54. SPSS. *SPSS 8.0 for Windows.* Chicago, Ill: SPSS Inc; 1998.
55. Carman KL, Short PF, Farley DO, et al. Early lessons from CAHPS demonstrations and evaluations. *Med Care.* 1999;37: MS97–MS105.
56. Fowler FJ Jr, Gallagher PM, Nederend S. Comparing telephone and mail responses to the CAHPS survey instrument. *Med Care.* 1999;37:MS41–MS49.
57. Dillman DA. *Mail and Internet Surveys: The Tailored Design Method.* 2nd ed. New York, NY: Wiley; 2000.
58. Novick M, Lewis G. Coefficient alpha and the reliability of composite measurements. *Psychometrika.* 1967;32:1–13.
59. Thompson RJ, Gustafson KE. *Adaptation to Chronic Childhood Illness.* Washington, DC: American Psychological Association; 1996.
60. Wallander JL, Varni JW. Effects of pediatric chronic physical disorders on child and family adjustment. *J Child Psychol Psychiatry.* 1998;39:29–46.
61. Newacheck PW, Hughes DC, Hung Y-Y, et al. The unmet health needs of America's children. *Pediatrics.* 2000;105:989–997.
62. Friedman B, Jee J, Steiner C, Bierman A. Tracking the State Children's Health Insurance Program with hospital data: national baselines, state variations, and some cautions. *Med Care Res Rev.* 1999;56:440–455.
63. Fiscella K, Franks P, Gold MR, Clancy CM. Inequality in quality: addressing socioeconomic, racial, and ethnic disparities in health care. *JAMA.* 2000;283:2579–2584.