

## The Clinical Utility of Health-related Quality of Life Assessment in Pediatric Cardiology Outpatient Practice

Karen Uzark, PhD, CPNP,\* Eileen King, PhD,<sup>†</sup> Robert Spicer, MD,<sup>‡</sup> Robert Beekman, MD,<sup>‡</sup> Thomas Kimball, MD,<sup>‡</sup> and James W. Varni, PhD<sup>§</sup>

\*Pediatric Cardiology, University of Michigan Mott Children's Hospital, Ann Arbor, Mich, <sup>†</sup>Division of Biostatistics & Epidemiology and <sup>‡</sup>Pediatric Cardiology, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, <sup>§</sup>Colleges of Architecture and Medicine, Texas A&M University, College Station, Tex, USA

### ABSTRACT

**Objectives.** Children with congenital heart disease may experience significant psychosocial morbidity related to impaired quality of life (QOL). The aim of this study was to evaluate the clinical utility of health-related QOL assessment in a pediatric cardiology outpatient clinic.

**Design.** The Pediatric Quality of Life Inventory (PedsQL) 4.0 Generic Core Scales were completed by a convenience sample of 176 patients, aged 8–18 years, being seen in a pediatric cardiology clinic. Three cardiologists enrolled in this study reviewed the completed PedsQL during the clinic visit and recorded their responses to items reported to be a problem “Often” or “Almost Always.” This utilization of the instrument was compared to standardized scoring and the practicality and perceived usefulness of the practice was evaluated by physician interview.

**Results.** PedsQL responses showed 38% of patients reporting significant (Often or Almost Always) problems on at least one domain (19% Physical Functioning, 18.2% Emotional Functioning, 11.4% Social Functioning, and 22.3% School Functioning problems). Using standardized scoring, the prevalence of scores below the cutoff score for clinically significant impaired QOL in each domain ranged from 10% to 20%, with agreement between scoring methods ranging from 89% to 93%, sensitivity 68% to 86%, and specificity 89% to 97%. Cardiologists reported interventions in 30.1% of patients. They found that the PedsQL was easy to use, did not interfere with clinic operations, required minimal time (1–5 minutes), and provided information that had an important impact on their practice in some patients.

**Conclusions.** This study demonstrates the clinical utility of health-related QOL assessment using the PedsQL in a pediatric cardiology outpatient setting. Identification of significant impairments in QOL can impact clinical decision making and may change psychosocial outcomes in children with congenital heart disease.

**Key Words.** Quality of Life; PedsQL; Pediatric Cardiology; Children; Patient-reported Outcomes

### Introduction

Health-related quality of life (QOL), a multidimensional construct which includes physical, psychological, and social functioning, has emerged as an important outcome in pediatric populations with chronic health conditions.<sup>1</sup> While QOL measurement has increasingly been incorporated as an outcome measure in adult and, more recently, pediatric research and clinical trials,<sup>2,3</sup> utilization of QOL assessment in clinical practice remains uncommon and few studies have assessed the value of QOL measurement in clinical practice.<sup>4,5</sup> Approximately one in five children with

heart disease reports significantly impaired psychosocial QOL, including children with mild or surgically corrected heart defects.<sup>6</sup> In children with more complex heart defects, the incidence of noncardiac morbidities is significantly higher.<sup>7</sup> Yet psychosocial problems remain the “hidden morbidity” in pediatric clinical practice.<sup>8</sup> The aim of this study was to evaluate the clinical utility of the Pediatric Quality of Life Inventory (PedsQL) 4.0 Generic Core Scales in a pediatric cardiology clinic, including the instrument’s usefulness related to identification of patient-specific problems prompting intervention, as well as the practicability and acceptability of utilization in the clinic setting.

## Methods

Three pediatric cardiologists were enrolled in this pilot study to assess the clinical utility of QOL assessment in a pediatric cardiology outpatient clinic. Informed consent was obtained. All were experienced cardiologists with busy clinic schedules. Patients with known heart disease, aged 8 to 18 years ( $n = 176$ ), completed the PedsQL<sup>9</sup> at a routine scheduled cardiology follow-up visit while waiting to see the cardiologist. The completed PedsQL was either placed in the patient's chart or given directly to the pediatric cardiologist by the family. The cardiologist was expected to (1) review the child's PedsQL responses, paying special attention to responses indicating that a problem occurred "Often" or "Almost Always" and (2) document action taken (intervention) in response to the identified problems utilizing a tracking form/checklist or in the letter to the child's primary care provider. The cardiologists were interviewed to ascertain their feelings about the practicality and usefulness of this method of QOL assessment in their clinic. The study was approved by the Institutional Review Board.

## Measures

The 23-item PedsQL 4.0 Generic Core Scales<sup>9</sup> encompass four domains: Physical Functioning (eight items), Emotional Functioning (five items), Social Functioning (five items), and School Functioning (five items). The PedsQL scales are comprised of parallel child self-report and parent proxy-report formats. Only the child self-report was used in this study. A 5-point Likert scale is utilized across child self-report for ages 8–18 (0 = Never a Problem; 1 = Almost Never a Problem; 2 = Sometimes a Problem; 3 = Often a Problem; 4 = Almost Always a Problem). Items are reverse-scored and linearly transformed to a 0–100 scale, so that higher scores indicate better QOL. Scores greater than one standard deviation (SD) below the population mean have been designated as a meaningful cutoff point score for an at-risk status for impaired QOL that is clinically significant relative to the pediatric population sample.<sup>10</sup> The reliability and validity of the PedsQL Generic Core Scales has been demonstrated in healthy and patient populations.<sup>9</sup> In this study, the PedsQL was not scored prior to the physician's review, rather the physician responded to individual items scored as 3 (Often) or 4 (Almost Always) a problem on the PedsQL itself, a method previously utilized in a pediatric rheumatology clinic.<sup>11</sup> In addition, a checklist of possible physician interventions or responses to the identi-

fied problems for each of the four QOL domains (physical, emotional, social, and school) was provided as well as the option of "other." For example, if a child indicated a problem related to physical functioning that did not seem consistent with the child's disease severity, the cardiologist might assess reasons for physical restrictions, provide education and counseling, do exercise testing, give an exercise prescription, etc. Finally, physicians were asked about the ease of use of the PedsQL, time required per patient, impact on clinic flow, importance or usefulness of the QOL assessment, and impact of the information on their practice.

## Statistical Analyses

Descriptive statistics were generated for demographic and clinical patient variables and are reported as means and SD for continuous variables and frequencies/proportions for categorical variables. Mean PedsQL Generic Core Scale scores were calculated for the Physical, Emotional, Social, and School Functioning scales. Individual scale scores were examined to determine the frequency of scores greater than 1 SD below the population sample mean, the cutoff score for clinical significance. The frequency of patients rating a problem a 3 (Often) or 4 (Almost Always) and the frequency of interventions in each domain were calculated and tested using Fisher's exact test. The relationship between PedsQL domain scores and provision of an intervention by the cardiologist was examined by the Wilcoxon rank-sum test. To determine the predictive value of assessment without formal scoring as utilized in this study, the relationship between a domain score in the clinically impaired range and a rating of 3 or 4 was examined by calculating diagnostic statistics such as sensitivity and specificity. The relationships between intervention and patient characteristics, including gender, race, and disease severity groups were assessed by Fisher's exact test and for age by the Wilcoxon rank-sum test. Descriptive data on the interviews with the physicians are also presented. All statistical tests were conducted at the two-sided 5% level of significance. SAS version 9.3 (SAS Institute, Cary, NC, USA) was used to perform statistical analysis.

## Results

The PedsQL 4.0 Generic Core Scales were completed by a convenience sample of 176 patients seen for follow-up in the pediatric cardiology clinic at Cincinnati Children's Hospital Medical Center.

**Table 1.** Prevalence of Patients Reporting Significant Problems by Domain (PedsQL Scale) (N = 176)

PedsQL Scale	% Patients with at Least 1 Item Scored Often/Almost Always a Problem	% Patients with at Least 2 Items Scored Often/Almost Always a Problem	% Patients below Cutoff Score—At Risk for Impaired HRQOL
Physical (8 items)	19%	9%	16%
Emotional (5 items)	18%	7%	10%
Social (5 items)	11%	6%	12%
School (5 items)	22%	10%	20%

PedsQL, Pediatric Quality of Life Inventory; HRQOL, health-related quality of life.

Patients ranged in age from 8.2 to 18.9 years (mean 12.8 years) and included 103 males and 73 females. The patient sample was predominantly Caucasian (90%). Approximately half (49%) had simple/ repaired disease defined as defects requiring no therapy or effectively treated nonoperatively (catheter therapy) or with “curative” surgical correction; the remaining 51% had more complex heart disease surgically treated with significant residua or need for additional surgeries, or uncorrectable or palliated lesions (including single ventricle). Nearly three fourths (70.5%) had undergone at least one cardiac surgical procedure.

#### Prevalence of Significant Problems and Physician Intervention

Review of the PedsQL responses showed 38% of patients reporting significant (Often or Almost Always) problems on at least one domain. As shown in Table 1, 19% reported a problem related to Physical Functioning, 18.2% Emotional Functioning problems, 11.4% Social Functioning problems, and 22.3% School Functioning problems, with 19% reporting problems in more than one domain. Table 1 also shows the proportion of patients reporting two or more problems within a domain, ranging from 6% to 10%, and the prevalence of scores below the cutoff score for clinically significant impaired QOL in each domain (range 10–20%). Cardiologists reported initiating interventions in 30.1% (53/176) of patients based on visual inspection of the PedsQL responses. For patients reporting significant problems, prevalence of physician intervention by domain was 30% for Physical Functioning, 50% for both Emotional Functioning and Social Functioning, and 54% for School Functioning. Specific interventions by domain are described in Table 2. With respect to physical problems, interventions (assessment of reasons for physical restrictions, counseling and prescription to encourage exercise, exercise testing, referral to obesity program) were prompted by problems related to difficulty

**Table 2.** Interventions in Response to PedsQL Information by Domain

Interventions	Count
Physical Functioning (N* = 22)	
Assessment of reasons for perceived physical restrictions	6
Education/Counseling	5
Exercise prescription	4
Consult/Referral	3
Exercise testing	2
Other	12
Emotional Functioning (N* = 26)	
Discuss fears/worries (reassurance)	10
Education/Counseling	6
Consult/Referral	5
Other	12
Social Functioning (N* = 20)	
Counseling if related to activity restrictions	7
Consult/Referral	4
Recommend family retreat/camp	3
Other	11
School Functioning (N* = 31)	
Child receiving special educational services	7
Referral for neuropsychological testing for evaluation and recommendations	3
Communication with school	2
Specialist to contact family	1
Other	25

Note: Physicians may have marked more than one intervention for a domain. \*N = number of patients who received an intervention related to the PedsQL domain.

PedsQL, Pediatric Quality of Life Inventory.

running in 6 of 10 patients and problems with doing sports or exercise in 6 of 11 patients, but were not offered in three of three patients with difficulty walking more than one block. With respect to emotional functioning, physicians most frequently intervened (provision of reassurance regarding fears and worries, referral for counseling through social worker or psychology) in response to the child’s worry about what was going to happen to them (7 of 12 patients), but less frequently to feelings of anger (three of nine patients). The most frequent social problem was not participating in peer activities which the physicians responded to (counseling, camp recommendation) in 5 of 10 patients. Physicians least frequently intervened in patients who found it dif-

**Table 3.** Relationship between PedsQL Scores and Subsequent Physician Response/Intervention

		Received Intervention	No Intervention	<i>P</i> value†
Physical (8 items)	Number of patients	22	154	
	Domain mean score*	75.0 ± 17.4	88.7 ± 14.0	<.0001
	% patients below cutoff for Impaired QOL	40.9%	13.0%	.003
	% patients with at least 1 item scored Often/Almost Always a Problem	45.4%	14.9%	.002
	% patients with at least 2 items scored Often/Almost Always a Problem	27.3%	6.5%	.007
Emotional (5 items)	Number of patients	26	150	
	Domain mean score*	65.6 ± 20.5	85.1 ± 16.0	<.0001
	% patients below cutoff for Impaired QOL	34.6%	6.0%	<.001
	% patients with at least 1 item scored Often/Almost Always a Problem	61.5%	10.7%	<.0001
	% patients with at least 2 items scored Often/Almost Always a Problem	19.2%	4.7%	.02
Social (5 items)	Number of patients	20	156	
	Domain mean score*	70.8 ± 22.4	88.6 ± 15.4	.0002
	% patients below cutoff for Impaired QOL	40.0%	9.0%	<.001
	% patients with at least 1 item scored Often/Almost Always a Problem	50.0%	6.4%	<.0001
	% patients with at least 2 items scored Often/Almost Always a Problem	25.0%	3.8%	.003
School (5 items)	Number of patients	31	145	
	Domain mean score*	55.2 ± 17.5	81.0 ± 15.7	<.0001
	% patients below cutoff for Impaired QOL	64.5%	11.0%	<.001
	% patients with at least 1 item scored Often/Almost Always a Problem	67.7%	12.4%	<.001
	% patients with at least 2 items scored Often/Almost Always	38.7%	3.5%	<.001

\*Mean ± standard deviation.

†*P* value for comparing means is from Wilcoxon rank-sum test. *P* value for comparing percentages is from Fisher's exact test. PedsQL, Pediatric Quality of Life Inventory.

difficult to make friends (one of four). School problems were responded to most frequently by the cardiologists (establishing the existence of an individualized educational plan or special education services, referral for neuropsychological testing) and included problems related to attention (14 of 17 patients), memory problems (10 of 18 patients), and difficulty keeping up with schoolwork (11 of 14 patients). Interventions were least frequent when problems were due to missed school for appointments or hospitalization (three of nine).

#### *Relationship between QOL Scores and Physician Response/Intervention*

Differences between QOL scores and the subsequent physician response with provision of an intervention based on the PedsQL findings are shown in Table 3. Mean PedsQL scores in patients who received interventions were significantly lower than scores for patients who did not receive interventions in each domain ( $P < .001$ ). Likewise, the proportion of patients with scores below the cutoff score for impaired QOL was significantly higher in the intervention group for all domains. Similarly,

the percentage of patients with significant problems based on item scores of 3 or 4 as utilized by the cardiologists in this study was significantly higher in the intervention group, with less than 5% of patients with two or more scores of 3 or 4 on emotional, social, or school domains in the group who did not receive an intervention (Table 3). Using at least one score of 3 (Often) or 4 (Almost Always) a problem as a surrogate for a PedsQL score below the cutoff for impaired QOL (1 SD below population mean), sensitivities range from 68% to 86% and specificities range from 89% to 97% (Table 4). The predictive value of the single-item rating method was 76%, 47%, 75%, and 74% for Physical, Emotional, Social, and School Functioning scales, respectively. Agreement between scoring methods ranged from 89% to 93%.

#### *Relationship between Patient Characteristics and Intervention*

There was no significant relationship between intervention and patient age ( $13.0 \pm 3.3$  in intervention group vs.  $12.7 \pm 3.0$  in no intervention group) or gender. As shown in Table 5, patients of

**Table 4.** Sensitivity, Specificity, and Predictive Value of Rating Method Utilized in Comparison to Standardized Scoring\*

	Sensitivity	Specificity	PPV	NPV	Agreement
Physical	86%	95%	76%	97%	93%
Emotional	83%	89%	47%	98%	89%
Social	68%	97%	75%	96%	93%
School	81%	93%	74%	95%	90%

\*Rating method = at least one item rating of 3 (Often) or 4 (Almost Always) a problem; PedsQL score below cutoff for at-risk for impaired quality of life used as gold standard for comparison.

PPV, positive predictive value; NPV, negative predictive value.

nonwhite race were more likely to receive interventions than patients of white race,  $P = .008$ . Patients with complex disease were more likely to receive interventions than patients with simple disease,  $P = .013$ . Similarly, patients with single ventricle were approximately twice as likely to have interventions in comparison to patients with biventricular heart defects,  $P = .009$ .

#### Cardiologists' Experiences

The three cardiologists reported that the PedsQL was easy to use and utilization did not interfere with clinic operations. It required on average 1–5 minutes of their time, dependent on identified patient problems. They felt that the information obtained was important and had an important or high impact on their practice in some patients. While some information was known to them through their standard history taking, especially related to physical functioning, “unexpected responses significantly influenced patient management decisions” in some patients.

#### Discussion

The data from this study support the clinical utility of the PedsQL 4.0 Generic Core Scales in a pediatric cardiology clinic. Clinical utility has been defined as “the ease and efficiency of use of an assessment, and the relevance and meaningfulness, clinically, of the information it provides.”<sup>12</sup> Thus, an examination of the impact of the assessment on clinical practice and routine work is an important part of the evaluation process. Our study has addressed a number of perceived barriers to measurement of health-related QOL in clinical practice previously identified by others including that: (1) measures are perceived as too long, impractical, and difficult to score; (2) information provided by QOL measurement is perceived to be already available through conventional interviewing or

history taking and as having no impact on clinical decision making; and (3) implementation of QOL measurement requires additional resources such as staff time and computer scoring systems and will interfere with clinic operation.<sup>4,13,14</sup> Our study reveals that using a brief measurement instrument (PedsQL) without formal scoring effectively identifies significant impairments in emotional, social, and school functioning in a significant number of children and adolescents with heart disease, identifying problems in approximately one in five patients. A simple method using ratings of “Often” or “Almost Always” a problem had acceptable sensitivity, specificity, and predictive value for most domains in comparison to formal scoring. The prevalence of psychosocial problems identified was consistent with our previously reported 21% incidence of significantly impaired psychosocial QOL in children 8 years of age and older with heart disease as determined using the established scoring methods for the instrument.<sup>5</sup>

The QOL information had an impact on clinical decision making in a significant proportion of patients, prompting interventions in 30%. In a multisite study of adults with chronic disease, Wasson and colleagues<sup>15</sup> found that “Health Status Assessment” using COOP Charts prompted physician action in 10% of patients at each return visit. More recently, Gutteling and colleagues<sup>4</sup> reported a significant impact of QOL information on patient management, with patient management altered in 11% of the experimental group with health-related QOL information available in contrast to 1% in the control group. Previous studies have suggested that identification of at-risk children with significant psychosocial problems allows targeted interventions which may actually avert future health care costs by ameliorating impaired QOL when first identified.<sup>16</sup> Finally, implementation of the QOL measurement utilizing the PedsQL did not require additional resources, required minimal additional physician time, and did not interfere with clinic flow or operation.

While physicians frequently intervened in response to identified problems on the PedsQL, it is important to understand the problems that did not prompt interventions. Some problems in physical functioning associated with disease severity may not be easily amenable to further medical or surgical intervention. However, when impaired physical functioning was not related to cardiac disease severity, but due to family- or self-imposed restrictions, then counseling and education, exer-

**Table 5.** Relationship between Patient Characteristics and Physician Response/Intervention

	Received Intervention	No Intervention	<i>P</i> value*
Age (mean ± SD)	13.0 ± 3.3	12.7 ± 3.0	.57
Gender			
Female (n = 73)	36%	64%	.19
Male (n = 103)	26%	74%	
Race			
White (n = 158)	27%	73%	.008
Nonwhite (n = 18)	61%	39%	
Severity			
Complex/Palliated (n = 90)	39%	61%	.013
Simple/Repaired (n = 86)	21%	79%	
Severity			
Single Ventricle (n = 21)	57%	43%	.009
Biventricular (n = 155)	26%	74%	

\**P* value for age is based on Wilcoxon rank-sum test. *P* value for percentages is based on Fisher's exact test. SD, standard deviation.

cise testing, and exercise prescription can potentially influence behavior and outcomes. With respect to psychosocial problems, physicians may lack adequate resources to manage these problems. The checklist of possible interventions provided was more limited related to some emotional and social problems. Problems with school functioning were most frequently addressed, as neurodevelopmental follow-up clinics are becoming more common and an increasing number of resources have been identified to evaluate and address these issues. However, school absence for illness or medical care may have been unavoidable.

The results of our study are among the first to show the utility and potential benefit of presenting QOL data to physicians in pediatric clinical practice. This pilot study also supports the clinical utility of the PedsQL as a practical and useful measure for identification of psychosocial problems in a pediatric cardiology setting with an impact on clinical decision making. Future studies should also explore the advantages of using disease-specific instruments such as the PedsQL Cardiac Module as the target for clinical interventions. The study has several limitations. The generalizability is somewhat limited by our predominantly Caucasian population. The data are from one children's hospital and included only three cardiologists. We did not include a control group of cardiologists who did not have PedsQL information in the pilot study and did not feel that it was feasible to randomize patients among the participating cardiologists and still measure interventions with accuracy and without bias related to study participation. Studies with more physicians, including less experienced cardiologists, are needed to establish the generalizability of our

findings. Comparison among the users is limited to the cardiologist's subjective evaluations of the process. Physicians vary in their knowledge of management strategies and perceived resources for managing psychosocial problems and the intervention checklists may have been insufficient. In addition, the impact of interventions on patient outcomes was not assessed in this pilot study and should be included in future studies through follow-up QOL assessment and in a randomized controlled trial. An important way in which the clinical utility of QOL assessment might be judged is by evaluating the degree to which the administration and feedback improves the outcome and quality of care. In a pediatric rheumatology clinic sample, PedsQL Generic Core Scale scores were significantly higher at follow-up when the pediatric rheumatologist made a clinical intervention based on prior PedsQL findings.<sup>11</sup> In a randomized controlled trial of adolescents with diabetes, using standardized scoring of the PedsQL completed on a computer prior to the appointment with the pediatrician, adolescents in the health-related QOL intervention group reported improved psychosocial QOL and higher self-esteem and satisfaction with care at follow-up than control subjects.<sup>17</sup> While we did not compare the impact of PedsQL utilization in clinical practice to routine care, the comments of participating cardiologists suggest that the PedsQL revealed "unexpected" problems in some patients and "increased their awareness of the impact of heart disease" on other areas of the patient's life, areas that would not have been captured with routine practice. Parents also expressed appreciation for our interest in these aspects of their child's daily life.

## Conclusion

This study demonstrates the clinical utility of health-related QOL assessment using the PedsQL in a pediatric cardiology outpatient setting. Identification of significant impairments of QOL can impact clinical decision making to potentially change these adverse psychosocial outcomes in children with congenital heart disease in the future.

## Author Contributions

Karen Uzark—Concept/design, drafting and revision of the article, approval.

Eileen King—Analysis and interpretation of data, critical revision, and approval of article.

Robert Spicer—Data acquisition, critical revision, and approval of the article.

Robert Beekman—Data acquisition, critical revision, and approval of the article.

Thomas Kimball—Data acquisition, critical revision, and approval of the article.

James W. Varni—Interpretation of the data, critical revision, and approval of article.

**Corresponding Author:** Karen Uzark, PhD, CPNP, University of Michigan Mott Children's Hospital, L2110 Women's, SPC 5202, 1500 East Medical Center Drive, Ann Arbor, MI 48109-5202, USA. Tel: (734) 615-9748; Fax: (734) 232-3744; E-mail: karenu@med.umich.edu

*Conflict of interest:* Dr. Varni holds the copyright and the trademark for the PedsQL and receives financial compensation from the Mapi Research Trust, which is a nonprofit research institute that charges distribution fees to for-profit companies that use the Pediatric Quality of Life Inventory. He did not receive compensation for the current project. The remaining authors have no conflicts of interest to disclose.

*Accepted in final form: August 4, 2012.*

## References

- Varni JW, Limbers CA, Burwinkle TM. Impaired health-related quality of life in children and adolescents with chronic conditions: a comparative analysis of 10 disease clusters and 33 disease categories/severities utilizing the PedsQL™ 4.0 Generic Core Scales. *Health Qual Life Outcomes*. 2007;5:1–15.
- Clarke SA, Eiser C. The measurement of health-related quality of life (QOL) in paediatric clinical trials: a systematic review. *Health Qual Life Outcomes*. 2004;2:66–70.
- Varni JW, Handen BL, Corey-Lisle PK, et al. Effect of Aripiprazole 2 to 15 mg/d on health-related quality of life in the treatment of irritability associated with Autistic Disorder in children: a post hoc analysis of two controlled trials. *Clin Ther*. 2012; 34:980–992.
- Varni JW, Burwinkle TM, Lane MM. Health-related quality of life measurement in pediatric clinical practice: an appraisal and precept for future research and application. *Health Qual Life Outcomes*. 2005;3:34–43.
- Gutteling JJ, Darlington ASE, Janssen HLA, Duivenvoorden HJ, Busschbach JJV, de Man RA. Effectiveness of health-related quality of life measurement in clinical practice: a prospective, randomized controlled trial in patients with chronic liver disease and their physicians. *Qual Life Res*. 2008;17:195–205.
- Uzark K, Jones K, Slusher J, Limbers C, Burwinkle TM, Varni JW. Quality of life in children with heart disease as perceived by children and parents. *Pediatrics*. 2008;121:e1060–e1067.
- McCordle BW, Williams RV, Mitchell PD, et al. Relationship of patient and medical characteristics to health status in children and adolescents after the Fontan procedure. *Circulation*. 2006;113:1123–1129.
- Costello EJ, Edelbrock C, Costello AJ, Dulcan MK, Burns BJ, Brent D. Psychopathology in pediatric primary care: the new hidden morbidity. *Pediatrics*. 1988;82:415–424.
- Varni JW, Seid M, Kurtin PS. Peds QL 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.
- Varni JW, Burwinkle TM, Seid M, Skarr D. The PedsQL 4.0 as a pediatric population health measure: feasibility, reliability, and validity. *Ambul Pediatr*. 2003;3:329–341.
- Varni JW, Seid M, Knight TS, Uzark K, Szer IS. The PedsQL 4.0 Generic Core Scales: sensitivity, responsiveness, and impact on clinical decision-making. *J Behav Med*. 2002;25:175–193.
- Smart A. A multi-dimensional model of clinical utility. *Int J Qual Health Care*. 2006;18:377–382.
- Gilbody SM, House AO, Sheldon T. Routine administration of health related quality of life (HRQoL) and needs assessment instruments to improve psychological outcomes—a systematic review. *Psychol Med*. 2002;32:1345–1356.
- Gutteling JJ, Busschbach JJV, de Man RA, Darlington ASE. Logistic feasibility of health related quality of life measurement in clinical practice: results of a prospective study in a large population of chronic liver patients. *Health Qual Life Outcomes*. 2008;6:97–105.
- Wasson J, Keller A, Rubenstein L, et al. Benefits and obstacles of health status assessment in ambulatory settings. *Med Care*. 1992;30:MS42–MS49.

- 16 Seid M, Varni JW, Segall D, Kurtin PS. Health-related quality of life as a predictor of pediatric healthcare costs: a two-year prospective cohort analysis. *Health Qual Life Outcomes*. 2004;2:48–57.
- 17 DeWit M, De Waal D, Bokma JA, et al. Monitoring and discussing health-related quality of life in adolescents with type1 diabetes improve psychosocial well-being. *Diabetes Care*. 2008;31:1521–1526.