The Pediatric Cardiac Quality of Life Inventory (PCQLI)

A disease-specific measure of health-related quality of life for children and adolescents with congenital or acquired heart disease

A brief user’s guide

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The PCQLI questionnaires, User’s Guide can be downloaded from the PCQLI website:

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Purpose (What is it?)

Health-related quality of life (HRQOL) refers to the perception of the impact of a specific illness, medical therapy, or health services policy on a person’s ability to participate and find satisfaction in life’s physical, psychological, and social experiences. The Pediatric Cardiac Quality of Life Inventory (PCQLI) is a disease-specific HRQOL instrument for children (8-12 years of age) and adolescents (13-18 years of age) with congenital or acquired heart disease (HD). This inventory was designed to address limitations of the current pediatric cardiac HRQOL instruments for the purpose of improving patient-centered medical treatment and outcome. The PCQLI is derived directly from concerns generated by patients, parent/guardians, and cardiac medical providers and incorporates both self-respondent and parent-proxy reporting.

Application (What are its applications?)

The PCQLI is intended for use in both clinical and research settings. Listed below are a few of the diagnostic, evaluative, and prognostic applications of this inventory:

Clinical
- Screening for medical and psychosocial problems
- Monitoring changes over time or in response to a specific therapy
- Better communication among patients, parents, and medical providers
- Prioritizing problems based partially on patient and/or parent preference

Research
- Cross-sectional and prospective studies of HRQOL
- Evaluating differences in clinically important subpopulations
- Determining treatment protocol efficacy
- Evaluating differences in therapeutic regimens
- Identifying modifiable morbidity factors
Description (What are the components, and what do they measure?)

The PCQLI consists of four pages with the first page stating the identity of the PCQLI respondent form (See Respondent Types and Forms). The main components of the PCQLI are the ‘General Health Perception Question’ and the inventory ‘items’. Items are categorized into specific ‘subscales’ for the purposes of scoring and analysis (See Scoring).

General Health Perception Question

The General Health Perception Question constitutes the entirety of page two of the inventory and is not considered an inventory ‘item’. It is a distinct question regarding overall health status and general quality of life (QOL). It is prefaced by “In general would you say your health is…” for self-respondent forms (Child Form, Adolescent Form) and by “In general would you say your child’s health is…” for parent-proxy forms (Parent of Child Form, Parent of Adolescent Form). Response options range from 1 (Excellent) to 5 (Poor) on a five-point Likert scale. Response values to the General Health Perception Question are not included in scoring.

Items

The individual questions that compose the PCQLI are referred to as ‘items’. All items are prefaced by “Because of my heart problem…” for self-respondent forms (Child Form, Adolescent Form) and by “Because of my child’s heart problem…” for parent-proxy forms (Parent of Child Form, Parent of Adolescent Form). Response options range from 1 (Strongly Agree) to 5 (Strongly Disagree) on a five-point Likert scale. All items are written at a 3rd grade Flesch-Kinkaid reading level.

Subscales

A ‘subscale’ is a grouping of related PCQLI items. Each of the three subscales represents the perceived effect of the patient’s heart condition on the ability of the patient to function in a distinct area: Disease Impact (physical functioning), Psychosocial Impact (psychological and social functioning), and Emotional Environment (emotional functioning). Items from the Disease Impact and Psychosocial Impact subscales constitute page three of the PCQLI, and items from the Emotional Environment subscale constitute page four. The response values to items in the Emotional Environment subscale are not included in scoring of the instrument.
Respondent Types and Forms (Why are there four forms?)

There are two types of respondents, self-respondents and parent-proxy respondents. ‘Self’ refers to the patient, and ‘parent’ refers to the parent or legal guardian. The PCQLI yields information from patient and parent perspectives as both may be important for thorough HRQOL analysis.\(^8\) Respondents are further subdivided on the basis of patient age into ‘Child’ (8-12 years of age) and ‘Adolescent’ (13-18 years of age) categories. These age ranges are derived from pubertal norms.\(^{11}\) As the concerns generated during development of the PCQLI differed between age categories, the items for the ‘Child’ category are non-identical to those of the ‘Adolescent’ category.\(^2\) The combination of respondent type and age category yield four PCQLI respondent forms: Child, Parent of Child, Adolescent, and Parent of Adolescent.

**Child**

The Child Form is a self-respondent form for patients 8-12 years of age. It is composed of 28 items, 14 belonging to the Disease Impact subscale, 9 belonging to the Psychosocial Impact subscale, and 5 belonging to the Emotional Environment subscale. Items are prefaced by, “Because of my heart problem…” and worded in the first person.

**Parent of Child**

The Parent of Child Form is a parent-proxy form for parent/guardians of patients 8-12 years of age. It is composed of 28 items, 14 belonging to the Disease Impact subscale, 9 belonging to the Psychosocial Impact subscale, and 5 belonging to the Emotional Environment subscale. These items are identical to those of the Child Form except that they are prefaced by, “Because of my child’s heart problem…” and worded in the third person.

**Adolescent**

The Adolescent Form is a self-respondent form for patients 13-18 years of age. It is composed of 37 items, 17 belonging to the Disease Impact subscale, 12 belonging to the Psychosocial Impact subscale, and 8 belonging to the Emotional Environment subscale. Items are prefaced by, “Because of my heart problem…” and worded in the first person.
Parent of Adolescent

The Parent of Adolescent Form is a parent-proxy form for parent/guardians of patients 12-18 years of age. It is composed of 37 items, 17 belonging to the Disease Impact subscale, 12 belonging to the Psychosocial Impact subscale, and 8 belonging to the Emotional Environment subscale. These items are identical to those of the Adolescent Form except that they are prefaced by, “Because of my child’s heart problem…” and worded in the third person.

Table 1. PCQLI Organization

<table>
<thead>
<tr>
<th>PCQLI Respondent Form</th>
<th>Page</th>
<th>Contents</th>
<th>Items in Subscale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child or Parent of Child</td>
<td>1</td>
<td>Form Identification</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>General Health Perception Question</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Disease Impact subscale</td>
<td>1-7, 9, 10, 12, 14, 18-20</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Psychosocial Impact subscale</td>
<td>8, 11, 13, 15-17, 21-23</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Emotional Environment subscale</td>
<td>1-5</td>
</tr>
<tr>
<td>Adolescent or Parent of Adolescent</td>
<td>1</td>
<td>Form Identification</td>
<td></td>
</tr>
<tr>
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<td>2</td>
<td>General Health Perception Question</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Disease Impact subscale</td>
<td>2-6, 8-12, 14, 15, 17-21</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Psychosocial Impact subscale</td>
<td>1, 7, 13, 16, 22-29</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Emotional Environment subscale</td>
<td>1-8</td>
</tr>
</tbody>
</table>

Initial Development (How were these questions generated?)

The PCQLI was developed through nominal group methodology and subsequent pilot instrument creation, feasibility evaluation (item analysis, principal-components analysis, internal consistency testing, analysis of patterns of correlation), and item reduction. The nominal groups that generated the PCQLI items consisted of pediatric cardiac patients (8-18 years of age), their parents, and cardiac medical providers.

Reliability and Validity Confirmation (Are these scores credible?)

Validation Population

The PCQLI validation population consisted of 1605 patient-parent pairs from seven, large, cardiac outpatient centers chosen for their geographic, ethnic, and racial diversity. Patients were eligible if they met the following criteria: 8-18 years of age, congenital or acquired HD, fluent in English, attending a routine outpatient visit. Patients were excluded if they lacked
fluency in English, were attending a non-routine visit (new patient, emergency or post-operative visit) or exhibited developmental delay or certain co-morbid conditions (e.g. diabetes, cancer, obesity, Trisomy 21). Select co-morbid conditions (e.g. Turner, Williams, Noonan, DiGeorge or Marfan syndrome or 22q11 microdeletion) did not result in exclusion. Parents of eligible patients were eligible unless they lacked fluency in English or exhibited developmental delay.

*Test-Retest Reliability*

Reliability of the PCQLI was confirmed by analyzing test-retest reliability of the PCQLI scores of the validation population. For test-retest reliability evaluation, patients and parents completed the PCQLI twice (baseline, retest). Baseline testing was completed at least 10 days before a routine outpatient cardiology visit. Re-testing was done on the day of the routine outpatient appointment before seeing their cardiology provider. Patients that had a change in their clinical status or patients and/or parents that experienced any significant life events (e.g. death of family member) between the baseline test and re-test were excluded from analysis. It was required that the same parent participate for both the baseline test and re-test. Correlations between baseline and re-test PCQLI scores were analyzed by respondent form (Child, Parent of Child, Adolescent, Parent of Adolescent) and PCQLI score (Disease Impact subscale score, Psychosocial Impact subscale score, Total score). All test-retest reliability correlations were excellent (>0.70) and statistically significant (p<0.001).

*Construct Validity*

Internal validity of the PCQLI was substantiated by analyzing construct validity of the baseline PCQLI scores of the validation population. The construct validity model had four components: 1) *known-groups method*: comparison of PCQLI scores between specific congenital HD subgroups derived from disease severity; 2) *analysis of variance*: variation of PCQLI scores with medical care utilization; 3) *convergent validity*: comparison of PCQLI scores to scores from generic HRQOL [Pediatric Quality of Life Inventory (PedsQL)] and non-quality of life [Self-Perception Profile for Children and Adolescents (SPPC/SPPA), Youth Self-Report/Child Behavior Checklist (YSR/CBCL)] instruments; and 4) *cross-informant variance*: comparison of patient and parent PCQLI scores. Lower PCQLI scores were associated with increased disease severity (p≤0.036), increased medical care utilization (p<0.001), poorer self-perception (PedsQL,
SPPC/SPPA; p<0.001) and competency (YSR/CBCL; p<0.001), and increased behavioral and emotional problems (YSR/CBCL; p<0.001). Correlations between patient and parent PCQLI scores were moderate to good (p<0.001).

**External Validity**

External validity of the PCQLI was confirmed by comparing the response option variability, scores (total, subscales), patterns of correlation (item-subscale, item-total, subscale-subscale, subscale-total), and internal consistency measurements of the validation population between the participants from the PCQLI development site (Development sample, 576 of 1,605 patient-parent pairs) and participants from the other six geographically diverse recruitment sites (Composite sample, 1,029 of 1,605 patient-parent pairs). All PCQLI items in both samples had enough variation in the patterns of responses chosen to allow for discriminatory scoring (i.e. no response was chosen >90% of the time for a single item). There were no significant differences between samples in the subscale or total PCQLI scores (p<0.008). Patterns of correlation between the Development and Composite samples were moderate (item-total, item-subscale) or high (subscale-subscale, subscale-total), and the PCQLI scores of both samples were internal consistent (Cronbach’s α >0.70).

**Responsiveness Testing** (Are these scores sensitive to changes over time?)

Responsiveness of the PCQLI is currently being evaluated with a pre- and post-intervention model. The study population consists of acquired or congenital HD patients undergoing radiofrequency ablation for arrhythmia, congenital heart surgery (aortic valve surgery, mitral valve surgery, right ventricle to pulmonary artery conduit replacement) or orthotopic heart transplantation and their parents. The PCQLI is administered pre-procedure, pre-discharge, and between 3-12 months post-procedure. For inclusion in the PCQLI Responsiveness population, patient and parents must meet criteria in addition to those of the validation population. Patients must be 8-12.9 years of age or 13-18.9 years of age for the duration of their participation. The same parent must participate for all tests. Patients and/or parents that experience any significant life events (e.g. death of family member) are excluded. PCQLI Responsiveness Testing is still in the enrollment and data collection phase.
**Administration** (How do I administer it?)

Subject Selection

Subject selection is at the user’s discretion. The PCQLI is reliable and valid for subjects that meet the inclusion and exclusion criteria of the validation population. The administration requirements will vary depending on the intended application of the inventory (See Application). Clinical and research administration guidelines are mentioned below.

**Clinical**

i. User’s discretion

ii. Administration procedure for validated PCQLI scores
   1. Pre-“routine” outpatient visit prior to seeing HCP
   2. Self-administered
   3. Patient with parent throughout administration
   4. Monitored to prevent parent-patient discussion
   5. Illiteracy protocol

iii. Cautionary advice (e.g. pre- vs post-HCP influences)

**Research**

iv. Informed Consent/Assent (Verbal)

v. PCQLI Administration
   1. Pre-“routine” outpatient visit prior to seeing HCP
   2. Self-administered
   3. Patient with parent throughout administration
   4. Monitored to prevent parent-patient discussion
   5. Illiteracy protocol
Scoring (How do I calculate the scores? What if there is missing data?)

Basic Calculations

The PCQLI generates three scores: Disease Impact subscale score, Psychosocial Impact subscale score, and Total score. Items from the Disease Impact and Psychosocial Impact subscales are intermixed on page three of each of the respondent forms. The specific items that constitute a scored subscale vary by respondent form according to the following table:

Table 2. Items in Scored Subscales

<table>
<thead>
<tr>
<th>Respondent Form</th>
<th>Subscale</th>
<th>Items in Subscale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child or Parent of Child</td>
<td>Disease Impact</td>
<td>1-7, 9, 10, 12, 14, 18-20</td>
</tr>
<tr>
<td></td>
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<td>8, 11, 13, 15-17, 21-23</td>
</tr>
<tr>
<td>Adolescent or Parent of Adolescent</td>
<td>Disease Impact</td>
<td>2-6, 8-12, 14, 15, 17-21</td>
</tr>
<tr>
<td></td>
<td>Psychosocial Impact</td>
<td>1, 7, 13, 16, 22-29</td>
</tr>
</tbody>
</table>

The Emotional Environment subscale is self-contained and its items are numbered separately from the Disease Impact and Psychosocial Impact subscales. The Emotional Environment subscale and General Health Perception Question are distinct and should not be included in scoring.

The Disease Impact and Psychosocial Impact subscale scores are calculated individually using the following formula:

\[
\frac{\sum \text{subscale item response values} - \text{Number of subscale items}}{4 \times \text{Number of subscale items}} \times 50 = \text{subscale score}
\]

The numerator, \( \sum \text{subscale item response values} - \text{Number of subscale items} \), adjusts the values from the Likert scale of 1-5 to an absolute scale of 0-4. The denominator, \( 4 \times \text{Number of subscale items} \), represents the maximum number of points possible on an absolute scale. The ratio is multiplied by the maximum subscale score of 50 to yield the subscale score.

The Total score is calculated from the Disease Impact and Psychosocial Impact subscales using the following formula:

\[
\text{Disease Impact subscale score} + \text{Psychosocial Impact subscale score} = \text{Total score}
\]

As the sum of these two subscale scores, the Total score has a maximum of 100 points possible.
Data Discrepancies

Common errors in inventory completion include missing responses, multiple responses for a single item, and extraneous information. For subscales missing less than three item responses, calculate the mean of the item response values for the subscale using the following formula:

$$\frac{\sum \text{subscale item response values}}{\text{Number of subscale items answered}} = \text{subscale mean item response value}$$

The subscale mean item response value should be rounded to two decimal places rather than nearest whole number. Substitute the subscale mean item response value for each missing item response in that subscale to allow for calculation of the subscale score. For subscales missing three or more item responses, do not calculate or include that subscale score or the Total score in analysis. Multiple responses to a single item are treated as ‘missing responses’ in regards to data manipulation and are counted as occurrences for the total number of permitted ‘missing responses.’ All extraneous information should be disregarded for the purposes of PCQLI scoring.

Access (Where can I obtain the questionnaires?)

Access to the PCQLI questionnaires requires registration of the user at the PCQLI website (http://www.pcqli.com). Registration facilitates proper inventory use and collaboration. PCQLI questionnaires will be provided as PDF files.

Non-profit (What does it cost? What are the terms of use?)

The PCQLI is a non-profit HRQOL measure for pediatric cardiac patients with acquired or congenital HD. There is no fee for using the PCQLI; however, its copyright is held by the Cincinnati Children’s Hospital Medical Center. Authorization to use this instrument for clinical and/or research purposes is contingent upon registration of the user and their agreement to give proper acknowledgement in any resulting publications. The PCQLI may not be used for profit nor may fees be charged for its administration.
References


