Published in final edited form as:
Pediatr Blood Cancer. 2012 October ; 59(4): 703–707. doi:10.1002/pbc.24099.

Feasibility, Reliability, and Validity of the Pediatric Quality of Life Inventory™ Generic Core Scales, Cancer Module, and Multidimensional Fatigue Scale in Long-Term Adult Survivors of Pediatric Cancer

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Abstract

Background—Most health-related quality of life assessments are designed for either children or adults and have not been evaluated for adolescent and young adult survivors of pediatric cancer. The objective of this study was to examine the feasibility, reliability, and validity of the Pediatric Quality of Life Inventory (PedsQL™) Generic Core Scales, Cancer Module, and Multidimensional Fatigue Scale in adult survivors of pediatric cancer.

Methods—Adult survivors ($n = 64$; Mean age 35 year old; > 2 years after treatment) completed the PedsQL™ Generic Core Scales, Cancer Module, and Multidimensional Fatigue Scale. Feasibility was examined with floor and ceiling effects; and internal consistency was determined by Cronbach's coefficient alpha calculations. Inter-factor correlations were also assessed.

Results—Significant ceiling effects were observed for the scales of social function, nausea, procedural anxiety, treatment anxiety, and communication. Internal consistency for all subscales was within the recommended ranges ($\alpha \geq 0.70$). Moderate to strong correlations between most Cancer Module and Generic Core Scales ($r = 0.25$ to $r = 0.76$) and between the Multidimensional Fatigue Scale and Generic Core Scales ($r = 0.37$ to $r = 0.73$).

Conclusions—The PedsQL™ Generic Core Scales, Cancer Module, and Multidimensional Fatigue Scale appear to be feasible for an older population of pediatric cancer survivors; however, some of the Cancer Module scales (nausea, procedural/treatment anxiety, and communication) were deemed not relevant for long-term survivors. More information is needed to determine whether the issues addressed by these modules are meaningful to long-term adult survivors of pediatric cancers.

Keywords

Quality of life

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Introduction

As the population of childhood cancer survivors grows [1,2], the late effects of cancer and its treatments, including effects on survivors' health-related quality of life (HRQOL), are becoming better understood. The self-reported health and well-being of childhood survivors are often worse than their age-related peers.[3-9] Their mental health may also be affected: survivors are at risk for mood, behavior, cognitive, and somatic problems [10-13]. Effects on quality of life manifest in different ways across time [12] and contribute to limited social autonomy and reach fewer achievement milestones, such as higher education, employment, independent living, and marriage [14-16].

To mitigate some of these effects, cancer survivorship clinics are being developed. These subspecialty clinics are intended to maximize survivors' quality of life. In such programs, academic, vocational, and psychological functioning are assessed, and survivors are provided with services such as clinical psychology, counseling psychology (career and vocational counseling), adolescent and young adult life services, neuropsychology, psychiatry, and educational guidance and advocacy.

Ideally, the assessment process determines which patients are in need of which psychosocial services. A semi-structured interview is a thorough method for screening psychosocial needs but is often impractical. An alternative screening method is a patient or proxy HRQOL report by means of a questionnaire administered either on paper or electronically. Variables considered in selecting an HRQOL screening tool include applicable age range, language versions available, proxy forms available that parallel self-reporting, and established reliability and validity for use with the clinic's population, which generates clinically relevant information and allows for clinical research.

When considering these issues in childhood cancer survivors, the Pediatric Quality of Life Inventory (PedsQL™; ©1998; MAPI Research TRUST, Lyon, France) tool for assessing HRQOL [17-23] appeared promising for the identified population and uses. HRQOL measures including the PedsQL™ are based on the assumption that health-related symptoms are causal indicators of general quality of life [24]. The PedsQL™ consists of generic modules, which apply to both healthy and chronically ill children, and disease- or health-problem-specific modules. The generic modules facilitate between-group comparisons, such as between healthy and high-illness-burden pediatric populations, whereas the disease-specific modules assess disease-specific symptoms. The reliability and validity of PedsQL™ have been established for newly diagnosed pediatric cancer patients, children with recurrent cancer, those in recent remission, and those who have completed treatment [22].

Although most HRQOL assessment tools, including PedsQL™, are designed for either children or adults (but not both) and few studies have been published on the adaptation and applicability of the teenager versions of the PedsQL™ Generic Core Scales, Cancer Module, and Multidimensional Fatigue Scale to 18-25-year-olds [24-26]. The teenager versions were adapted to the older age group by adding work to the school and classroom items and by referring to young adults rather than teens. The young adult versions have been received well by healthy college students, young adults undergoing cancer treatment, and those with chronic blood disorders [24,26].

However, the PedsQL™ has not been applied to persons older than 25 years of age, nor has it been applied to young adults who are long-term survivors of pediatric cancer. At The University of Texas MD Anderson Cancer Center, the majority of pediatric cancer survivors served in the survivorship clinic are in their 20s, which is beyond the age range for which PedsQL™ was initially designed. In addition, the patients are several years past illness and treatment. Thus, the suitability of the PedsQL™ for this population is not known. The aim of this study was to assess the feasibility, reliability, and validity of using the PedsQL™ for long-term survivors of childhood cancer who are 25 years and older.

Methods

We administered the PedsQL™ Generic Core Scales, Cancer Module, and Multidimensional Fatigue Scale to English- and Spanish-speaking survivors of childhood cancer (> 2 years after treatment) participating in the MD Anderson's survivorship clinic between December 2008 and July 2010. The English and Spanish versions of PedsQL™ were used and a user agreement was established with Dr. James W. Varni, licensor and author of the PedsQL™ and the MAPI Research Trust. [24-26]. Participants completed the PedsQL™ on the day of their annual medical appointment, prior to the visit with the primary physician, and the information was used during the examination. The staff member presenting the questionnaire held a master's degree in psychology and assisted in the event the patient had questions. This study was approved by the MD Anderson Institutional Review Board.

PedsQL™

We used the PedsQL™ Generic Core Scales (version 4.0), Cancer Module (version 3.0), and Multidimensional Fatigue Scale. The Generic Core Scales consisted of 23 items and 4 scales, which measured physical, emotional, social, and school (as well as work for the young adults) function. The Cancer Module consisted of 27 items and 8 scales: pain, nausea, procedural anxiety, treatment anxiety, outcome anxiety, cognitive problems, physical appearance, and communication. The Multidimensional Fatigue Scale consisted of 18 items and 3 scales: general fatigue, sleep/rest fatigue, and cognitive fatigue. Each item was scored on a 5-point Likert scale from 0 to 4 (i.e., 0 = never, 1 = almost never, 2 = sometimes, 3 = often, 4 = almost always). Individual item scores of 0-4 were reverse-scored and linearly transformed to a 0 to 100 scale, with higher scores indicating better quality of life and fewer symptoms. Hence, a 0 in Likert scale transformed into a score of 100, and 4 in Likert scale transformed into a score of 0. The scale score varies in 25 point increments from 0 to 100. All scales had multiple items, which were summed and divided by the number of items, to provide a scale score. The three modules took 15 to 20 minutes to complete.

Statistical Analysis

Medical and demographic characteristics were analyzed descriptively. Feasibility was calculated by floor and ceiling effects, as well as the percentage of missing responses. Using linearly transformed scores, floor and ceiling effects were measured by the percentage of lowest (a score of 0) and highest (a score of 100) possible scores. Internal consistency was determined by Cronbach's coefficient alpha calculations of the individual HRQOL scales. Spearman correlation coefficients were utilized to assess the relationships between scales measuring disease-specific symptoms (in the Cancer Module and Multidimensional Fatigue Scale) and general quality of life (in the Generic Core Scales). Medium (0.30-0.49) to large (≥0.50) effect sizes would indicate significant relationships between symptoms and quality of life. Statistical significance was determined at alpha ≤ 0.05.

Results

One-hundred seventy patients were identified as potential participants. Thirteen patients declined participation. Two patients were not eligible due to cognitive impairment. Sixty-four were at least twenty-five years of age and completed adapted versions of the PedsQL™. Characteristics of study participants are reported in Table I. Most of the participants were female, white, between the ages of 25 and 40 years, and diagnosed with a solid tumor about 26 years ago.

Feasibility

Because the PedsQL™ was originally designed for teenagers between 13 and 18 years of age, we wanted to make sure that our participants did not find the questions irrelevant. Three participants did not respond to an item. The item omitted was different in each case (pertaining to running, sleeping, and worrying). One participant did not complete the Multidimensional Fatigue Scale; this equates to a missingness of less than 2% for these items. The participants were cooperative, with some explaining their rationale for the score assigned to an item.

Floor and ceiling effects are shown in Table II. Participants' mean scores ranged from 65.8 for the pain and hurt scale (Cancer Module) to 92.5 for the nausea scale (Cancer Module). No significant floor effects were found. Zero to 8% of survivors reported the lowest possible score on 1 or more scales. The lowest scores mean scores were observed on the Cancer Module's scale of pain and hurt and the Multidimensional Fatigue Scale of sleep/rest fatigue.

Significant ceiling effects were found, meaning that >15% of the sample population achieved the highest possible scale score, indicating better functioning. Two to 67% of survivors reported the highest possible value on 1 or more scales. The highest scores were observed on the Cancer Module scales of nausea, procedural anxiety, treatment anxiety, and communication.

Internal Consistency

Cronbach's alpha values were used to determine internal consistency of the scales (see Table II). All internal consistency scores for the scales were within the recommended range ($\alpha \geq 0.70$). Eighteen (95%) of the 19 scales had a Cronbach's alpha value of 0.75 or greater. Eight scales had a Cronbach's alpha value of 0.90 or greater: Generic Core Scales total, physical health, psychosocial health; Cancer Module total, pain and hurt; Fatigue Scale total, general fatigue, and cognitive fatigue. The third Multidimensional Fatigue scale of sleep/rest fatigue had a Cronbach's alpha value of 0.88, which, combined with the high Cronbach's alpha values for the other Multidimensional Fatigue scales, suggests that this module could be used to analyze individual patient scale scores for long-term survivors of pediatric cancer.

Inter-scale correlations

We calculated Spearman correlation coefficients to assess the relationship between physical symptoms, as measured by the Cancer Module and Multidimensional Fatigue Scale, and general quality of life, as measured by the Generic Core Scales (Table III). Most Cancer Module scales were significantly correlated with the Generic Core scales; exceptions were in the procedural anxiety and treatment anxiety scales, with the relationship between perceived physical appearance and emotional support being borderline significant ($P = 0.052$). Otherwise, the correlations between Cancer and Generic Core scales ranged from r = 0.25 to r = 0.81. All associations were positive (high scores were associated with high scores). All Multidimensional Fatigue scales were significantly correlated with scales on the Generic Core scales, with correlation coefficients ranging from r = 0.27 to r = 0.73.

Discussion

Our analyses support the application of the PedsQL™ to long-term survivors of childhood cancer who are at least twenty-five years old. The young adult versions of the PedsQL™ appeared to be feasible for use in long-term survivors of pediatric cancer, with adults leaving minimal items blank, demonstrating willingness to complete the forms. Internal consistency was adequate, indicating that the items contained in each scale are succinct constructs. Overall, our study provides preliminary data on the practical use of the PedsQL™ among an older population of pediatric cancer survivors.

The Cancer Module, however, requires modification for use in this population. Significant ceiling effects highlight the issue of sampling domain relevance. Ceiling effects indicate that high functioning patients have reached the higher end of the scale range for well-being, and the problems being sampled are not relevant for the targeted population.

The Cancer Module's nausea, procedural anxiety, treatment anxiety, and communication (with treatment providers) scales showed significant ceiling effects, suggesting that many long-term survivors of pediatric cancer are not concerned with or do not experience deficits in these domains. Even pediatric oncology patients off-treatment for as few as 13 months have reported significantly less nausea, treatment anxiety, and outcome anxiety as compared with patients in active treatment.[19] Nausea, treatment anxiety, procedural anxiety, and communication (with treatment providers) were largely deemed not relevant by those sampled in this study.

The Generic Core social functions scale also showed significant ceiling effects. The items on this scale are limited to peer-based relationships and friendships; the types of social functions queried might need to be broadened to include romantic relationships.

Furthermore, some issues that pertain to long-term survivors of pediatric cancer [14,27-31] are not addressed in the PedsQL™. For example, this population is at increased risk to develop chronic health conditions such as major organ dysfunction, sensory deficits, and infertility [32-35]. Such health conditions would likely impact a survivor's independence, romantic relationships, sexuality, career, and financial situation. The development of a Pediatric Cancer Late Effects module might complement available PedsQL™ resources.

One potential limitation of our study is that the participants may not represent pediatric cancer survivors as a whole. This sample represents survivors who are vigilant about annual medical follow-up and disease surveillance. They may be quite different in their quality of life compared with those who are not proactive in managing their preventative efforts. In addition, our sample size was not large enough to conduct analyses (e.g., factor analysis) to establish the construct validity of this instrument and our study population may not be homogenous due to the wide age range and several cancer diagnoses represented. That being said, our study strengths include use of valid HRQOL measures and a unique population of childhood cancer survivors.

In conclusion, the PedsQL™ appears to be an adequate instrument to measure HRQOL among childhood cancer survivors who are further out from diagnosis and at least twenty-five year old. The data supports the feasibility of the PedsQL™ and provides meaningful insight into the continued adaptation and validation of this instrument among older populations. More research is needed to support the structural aspects of validity in older populations of pediatric cancer survivors. Furthermore, future studies should examine the measurement equivalence/invariance of HRQOL subscales among adolescent and adult survivors of pediatric cancer. Demonstrating that the measurement characteristics are consistent between these two distinct age groups will validate the appropriateness of using the PedsQL™ in adult populations.

Acknowledgments

This project was financially supported by the Astros' Baseball Team Long-Term Survivor Fund and the National Institutes of Health through MD Anderson's Cancer Center Support Grant CA016672.

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Table I

Characteristics of participating survivors (N = 64)

Characteristic	Value
Current age, mean ± SD, years	34.5 (7.4)
Minimum, Maximum	25, 53
Age at diagnosis, mean ±SD, years	9.6 (5.3)
Minimum, Maximum	1, 21
Years since diagnosis, mean ± SD	25.2 (9.3)
Minimum, Maximum	5, 43
Sex, n (%)	
Female	38 (59.4)
Male	26 (40.6)
Cancer diagnosis, n (%)	
Central nervous system tumor	9 (14.1)
Hematological/leukemia	11 (17.2)
Lymphoma	11 (17.2)
Solid tumor	33 (51.6)
Ethnicity, n (%)	
Asian	2 (3.1)
Black	5 (7.8)
Hispanic	15 (23.4)
White	42 (65.6)

SD, standard deviation.

Table II

Mean scale scores, Chronbach's alpha, and floor and ceiling effects for the PedsQL™

Instrument	No. of items	M (SD)	α	Floor, %	Ceiling, %
Generic Core Scales					
Total Generic score	23	78.2 (17.0)	0.93	0	2
Physical health	8	73.8 (25.0)	0.92	0	13
Psychosocial health	15	80.6 (15.6)	0.90	0	3
Emotional function	5	74.2 (20.3)	0.85	0	13
Social function	5	88.7 (16.6)	0.83	0	48
School/work function	5	79.0 (19.4)	0.84	0	19
Cancer Module					
Total Cancer score	27	81.3 (14.6)	0.91	0	3
Pain and hurt	2	65.8 (30.1)	0.91	8	23
Nausea	5	92.5 (11.5)	0.83	0	59
Procedural anxiety	3	90.6 (17.7)	0.82	0	67
Treatment anxiety	3	87.5 (17.8)	0.86	0	59
Worry	3	73.0 (20.6)	0.70	0	20
Cognitive problems	5	81.6 (21.2)	0.88	2	28
Perceived physical appearance	3	77.5 (23.6)	0.85	2	28
Communication	3	87.8 (19.3)	0.85	5	63
Multidimensional Fatigue Scale					
Total Fatigue score	18	71.5 (20.0)	0.95	0	3
General fatigue	6	70.5 (24.7)	0.94	3	9
Sleep/Rest fatigue	6	67.1 (23.2)	0.88	0	8
Cognitive fatigue	6	77.0 (23.9)	0.96	2	30

M = mean PedsQL™ scale score, ranging from 0 to 100, with higher scores representing better function; SD = standard deviation; α = Chronbach's coefficient alpha, a measure of internal consistency; Floor, % = % of participants endorsing the lowest possible scale score of 0; Ceiling, % = % of participants endorsing the highest possible scale score of 100.

Table III

Spearman coefficients of correlation between the PedsQL™ Cancer Module, Multidimensional Fatigue Scale, and Generic Core Scales

	Generic Core Scales					
Instrument	**Tot Gen**	**Ph**	**Psy**	**Em**	**Soc**	**Sch/Wrk**
Cancer Module						
Total Cancer score	0.76	0.56	0.81	0.66	0.52	0.69
Pain and hurt	0.75	0.71	0.63	0.54	0.45	0.51
Nausea	0.47	0.45	0.44	0.35	0.38	0.35
Procedural anxiety	0.37	0.36	0.32	0.19 (ns)	0.25	0.30
Treatment anxiety	0.30	0.06 (ns)	0.48	0.52	0.16 (ns)	0.33
Worry	0.58	0.43	0.62	0.56	0.30	0.53
Cognitive problems	0.63	0.44	0.70	0.52	0.57	0.62
Perceived physical appearance	0.40	0.28	0.43	0.24 (ns)	0.39	0.42
Communication	0.51	0.36	0.58	0.39	0.54	0.53
Multidimensional Fatigue Scale						
Total Fatigue Score	0.71	0.56	0.69	0.60	0.48	0.62
General fatigue	0.73	0.61	0.67	0.59	0.49	0.58
Sleep/rest fatigue	0.51	0.39	0.54	0.57	0.27	0.45
Cognitive fatigue	0.54	0.43	0.53	0.32	0.50	0.56

TotGen = Total Generic Core score; Ph = physical health; Psy = psychosocial health; Em= emotional functioning; Soc = social functioning; Sch/Wrk = school or work functioning; All correlations not marked “(ns)” are significant at $p < 0.05$.