

Development and psychometric evaluation of the TAPQOL: A health-related quality of life instrument for 1–5-year-old children

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Abstract

The 43-item TNO-AZL Preschool Children Quality of Life (TAPQOL) questionnaire was developed to meet the need for a reliable and valid instrument for measuring parent's perceptions of health-related quality of life (HRQoL) in preschool children. HRQoL was defined as health status in 12 domains weighted by the impact of the health status problems on well-being. The aim of this study was to evaluate the psychometric performance of the TAPQOL. A sample of 121 parents of preterm children completed the TAPQOL questionnaire (response rate 88%) as well as 362 parents of children from the general population (response rate 60%). On the base of Cronbach's α , item-rest correlation, and principal component analysis, the TAPQOL scales were constructed from the data for the preterm children sample. The psychometric performance of these scales was evaluated for both the preterm children sample and the general population sample. Cronbach's α ranged from 0.66 to 0.88 for the preterm children sample and from 0.43 to 0.84 for the general population sample. The unidimensionality of the separate scales was confirmed by principal component analysis for both the preterm children sample and the general population sample. Spearman's correlation coefficients between scales were, on average, low. *T*-tests showed that the very preterm children, the children with chronic diseases, the less healthy and the less happy children had lower mean scores on the TAPQOL scales than healthy children, indicating a worse quality of life. This study shows that the TAPQOL is a reliable and valid parent's perception of HRQoL in preschool children. More research is needed to evaluate the psychometric performance of the TAPQOL in different clinical populations.

Key words: Health-related quality of life, Preschool children, Preterm birth, Quality of life instruments

Introduction

The application of health-related quality of life (HRQoL) as an outcome measure in medical care has increased enormously during the last decades. For children, however, less HRQoL instruments are developed than for adults. For preschool children in particular, only a few instruments are available, examples being the RAND and the FS-II(R) [1, 2]. These instruments are certainly useful, although they do not measure HRQoL as a multi-dimensional construct. It is suggested by

several authors that a multi-dimensional approach is preferred when measuring health outcomes, in order to capture the full range of manifestations of health and illness [3–6].

This lack of multi-dimensional HRQoL instruments for children may be due to two major methodological problems. The first one is the proxy problem. Young children are unable to complete a questionnaire themselves, so the help of a proxy is needed. In measuring children's HRQoL, parents are commonly used as proxy respondents. The validity of using proxies as

respondents in health surveys has been the issue of many studies, showing partial agreement between proxy-report and self-report. Existing evidence suggests that, as in adult patients, agreement between proxy-report and self-report depends on the observability of the domain [7–11]. In addition, proxies consistently reported less dysfunction in psychological domains than did children themselves [12–14].

The second problem is the age-specific development of children in several health-related domains. It is impossible to include the whole development of 0–18-year-old children in one HRQoL-instrument. Age-specific instruments are needed when measuring HRQoL in children.

Since many diseases are no longer fatal, the outcome assessment of different treatments has shifted from mortality to functional health status, quality of life and well-being. Many young children with chronic diseases are surviving and receiving different treatments. To evaluate the effects of different treatments of (chronically) ill children on their well-being, a valid and reliable multi-dimensional HRQoL instrument for preschool children is needed. Such an instrument will be useful in measuring the impact of diseases and treatments on the different domains of young children's lives. To meet this need for a reliable and valid instrument measuring HRQoL in very young children, the TNO-AZL Preschool Children Quality of Life (TAPQOL) questionnaire was developed: a generic, multi-dimensional HRQoL instrument for 1–5-year-old children. Self-reports are virtually impossible to obtain in preschool children and therefore the agreement between self-report and proxy report in these children cannot be studied. Consequently, what is being measured by the TAPQOL is the parent's perception of their child's HRQoL. The TAPQOL covers 12 (sub)domains thought to be relevant for children between 1 and 5.

It has been pointed out that, when measuring HRQoL, it is important not only to include health status but also the negative emotions that are elicited by limitations in health status [15–17]. In accordance with these suggestions, in developing the TAPQOL, HRQoL is defined in relation to, but clearly distinguished from, the concept of Health Status. Health Status refers to functioning in various domains. HRQoL includes the person's

well-being in relation to problems and limitations in functioning. Consequently, the TAPQOL assesses functional problems weighted by the degree to which a child shows negative emotions to such problems. The TAPQOL has to be filled in by one of the parents of the child.

The aim of the present study was to evaluate the psychometric performance of the TAPQOL.

Material and methods

TAPQOL questionnaire and scales

An inspection of existing questionnaires and literature and discussions with HRQoL experts, paediatricians, psychologists and parents of 1–5-year-old children showed that, in general, the following (sub)domains are considered essential for 1–5-year-old children: symptoms, sleeping, appetite, motor functioning, social functioning, problem behaviour, communication, and positive and negative emotional functioning.

It is widely accepted that HRQoL includes four domains: physical functioning, social functioning, cognitive functioning and emotional functioning. The selected (sub)domains for the TAPQoL can be assigned to the four main HRQOL domains in the following way: physical functioning includes symptoms, sleeping, appetite, motor functioning. Social functioning includes problem behaviour and social functioning. Cognitive functioning includes communication. Emotional functioning includes positive and negative emotional functioning.

These (sub)domains were included in the definition of HRQoL to be measured. Based on literature, psychological and clinical experience, a preliminary version of the questionnaire was made by selecting a number of items for every (sub)domain. The feasibility of this preliminary version of the TAPQOL questionnaire was evaluated in a group of parents of 1–5-year-old children. Several items were deleted or rephrased after this feasibility pilot. Using the data for the preterm children (sample 1), the final TAPQOL scales were constructed, using classical psychometric procedures, including Cronbach's α , item-rest correlation, and principal component analysis. The number of items was reduced from 99 to 43 items in the final TAPQOL questionnaire. Analysis indicated that

the domain symptoms covered three scales, namely lung problems, stomach problems and skin problems. The domain of emotional functioning also covered three scales, namely anxiety, positive mood and liveliness. Consequently, the final TAPQOL consists of the following 12 scales presented in Figure 1.

The number of items per scale varies from 3 to 7. Scale scores were obtained by adding item scores within scales, and transforming crude scale scores linearly to a 0–100 scale, with higher scores indicating better quality of life. The scales measuring motor functioning, social functioning and communication are applicable only to children 1.5 years and older, because these domains relate to age-specific problems that are not applicable to children younger than 1.5 years. Parents are asked to report problems that occurred in the last 3 months. All 43 items of the TAPQOL are presented in Appendix A. The English version of the TAPQOL, translated from Dutch in accordance with international guidelines [18], is available on request.

Item construction and weighting

In the scales for measuring sleeping, appetite, lung problems, stomach problems, skin problems, motor functioning, and communication, items consist of two questions. In these items, the frequency of a specific complaint or limitation during the last 3 months is first recorded. If such a problem is reported, the well-being of the child in relation to this problem as rated by the parents is assessed. In the feasibility study, parents indicated that they had no problem judging the well-being of their child in case of a health status problem. An item-example is presented in Figure 2. Each item is encoded into one single score, ranging from 0 to 4. A score of 4 is given if the child has no problem; a score of 3 if the child has a problem (i.e. occasionally or often) but

the child feels ‘fine’ during the problem; a score of 2 if the child has a problem and feels ‘not so good’; a score of 1 if the child has a problem and feels ‘quite bad’; and a score of 0 if the child has a problem and feels ‘bad’. Functional problems are therefore weighted according to their impact on well-being. The different items of every scale are added up, with higher scores representing better HRQoL.

In the scales measuring social functioning, problem behaviour, anxiety, positive mood and liveliness, the items measure only the frequency of a specific complaint or limitation during the last 3 months. In the items in these domains, it is not asked how the child feels since the items in these domains already imply a positive or negative emotional state. In these scales, each item score ranges from 0 to 2. An example is presented in Figure 3. A score of 2 is given if the child ‘never’ has a problem; a score of 1 if the child ‘occasionally’ has a problem and a score of 0 if the child ‘often’ has a problem.

FS-II(R) and other variables

Apart from the TAPQOL-questionnaire, parents were asked to fill in questions on demographics, children’s chronic diseases, common illnesses and recent medical treatment of their child. Furthermore, the parents version of the FS-II(R), a 14-item measure of children’s health status [1, 2], was used to evaluate concurrent validity. The FS-II(R) is a validated health status measurement that discriminates between healthy and less healthy children [2, 19]. For example, children with asthma have a lower score on the FS-II(R) than children without asthma.

Procedure

A set of items was administered to parents of a group of preterm children, and to parents of a

Physical functioning	Social functioning	Cognitive functioning	Emotional functioning
Sleeping	Problem behaviour	Communication	Positive mood
Appetite	Social functioning		Anxiety
Lung problems			Liveliness
Stomach problems			
Skin problems			
Motor functioning			

Figure 1. The TAPQOL scales.

In the last three months, has your child been...

Short of breath? never [4] occasionally often

At that time, my child felt:

fine [3] not so good [2] quite bad [1] bad [0]

Figure 2. Item example TAPQOL (the scores attributed to the paired items are in italics).

How was your child in the last three months?

In good spirits never [2] occasionally [1] often [0]

Figure 3. Item example TAPQOL (the scores are in italics).

group of children from the general population. On the basis of the data from the preterm children sample, we selected items to construct a final measure. We evaluated that measure on psychometric criteria includes reliability, construct validity, concurrent validity and criterion validity.

Paediatricians of the Leiden University Medical Centre wanted to include HRQoL as part of an extensive follow-up study of preterm children. A preterm sample (sample 1) was therefore included in the study for the development of the TAPQOL. A second sample from the open population (sample 2) was included, as the TAPQOL should be a generic measurement suitable for different populations.

Sample 1

Periodically, parents with a preterm child visit an out-patient neonatology clinic for a regular examination of their child's health during the early years. Between July and December 1996, all the parents of 138 preterm children aged 1–5 who visited the out-patient neonatology clinic of the Leiden University Medical Centre in the Netherlands were invited to fill out a set of questions. Completed questionnaires were returned by mail.

Sample 2

Periodically, almost all (98%) children aged 0–5 in the Netherlands visit well-baby clinics. During a 6-month period, the nurses from six well-baby clinics passed out the questionnaire to the first 100 parents who visited their clinic with a child aged

1–5. All visiting parents were invited to complete a set of questionnaires, except those parents who spoke no Dutch. Almost all parents were willing to fill out the questionnaire. Completed questionnaires were returned by mail.

Analyses

Scale scores were obtained by adding item scores within scales, and transforming crude scale scores linearly to a 0–100 scale, with higher scores indicating better quality of life.

Reliability was evaluated by calculating Cronbach's α for each scale.

Construct validity was evaluated by means of several procedures. Since the item scores are a combination of functional problems weighted by the degree to which a child shows negative emotions to such problems, the ordinality of these final item scores was checked. Homogeneity Analysis (HOMALS) was performed to check the ordinality of the scores. We assumed that the category quantifications should show a distinct order in the categories.

The unidimensionality of the separate scales was evaluated by Principal Component Analysis and by calculating item-rest and item scale correlation coefficients. The relationships between the 12 different scales of the TAPQOL were evaluated by calculating Spearman's (ρ) correlation coefficients between the TAPQOL scales.

The validity of the distinction between health status problems and the (negative) impact on well-being of such problems was evaluated by

calculating the total number of health status problems and the percentage of such problems that led to a negative feeling for the child. The total number of health status problems was computed by dichotomizing every health-status item into 'no problem' (never) vs. 'a problem' (occasionally/often). Thus for a four-item domain, for example, 'sleeping', every child could have minimum of 0 and maximum of four health problems.

Concurrent validity was evaluated by calculating Spearman's (ρ) correlation coefficients between the TAPQOL scales and the FS-II(R) score.

Criterion validity was evaluated by relating the TAPQOL scale scores to four dichotomous criteria by means of *T*-tests.

1. Healthy children from the general population sample were compared with preterm children with a gestational age of less than 32 weeks, the last being a group with an expected less good health than the general population [20–22].
2. Children in the general population sample suffering from any chronic disease were compared with children that did not suffer from a chronic disease.
3. Parents were asked how healthy their child was. Children with good health (according to the parents) were compared with children with less good health.
4. Parents were asked how happy their child was. Children who were very happy (according to the parents) were compared with children who were less happy.

Results

Sample 1

Respondents

Response rate in the group of parents of preterm children was 88% ($n = 121$). All children had a gestational age of <37 weeks. The sample included 65 children with a gestational age of <32 weeks. The percentage of girls of the sample was 42%. The age of the children ranged from 10 to 60 months: 45% of the children were between 10 and 24 months old, 30% between 24 and 36 months old, 12% between 36 and 48 months old and 13% between 48 and 60 months old.

Distribution and reliability

The categorised percentile distributions presented in Table 1 show that the scores on the TAPQOL scales were skewed. The percentage of missing was low: for most scales less than 5%. Cronbach's α ranged from 0.66 to 0.88. For only one scale, i.e. 'stomach problems', the Cronbach's α was below 0.70.

Construct validity

The sample was too small to perform HOMALS analysis meaningfully, so this analysis was only performed for sample 2. For each set of items belonging to a scale a separate principal component analysis was performed. All these analyses resulted in only one factor being extracted indicating the unidimensionality of the scales. All

Table 1. Cronbach's α and categorised percentual distribution of the TAPQOL scales for the preterm children sample ($n = 109$)

Scale	Number of items	Cronbach's α	Missing (%)	Categorised percentual distribution Scale: 0–100				
				0–24	25–49	50–74	75–99	100
Sleeping	4	0.88	0	1	5	31	34	29
Appetite	3	0.79	1.8	1	1	11	53	34
Lungs	3	0.83	2.8	0	6	16	18	60
Stomach	3	0.66	1.8	1	4	14	32	49
Skin	3	0.79	0	1	0	7	50	42
Motor functioning	4	0.77	5.1	0	1	8	41	50
Social functioning	3	0.75	5.1	1	0	18	27	54
Problem behaviour	7	0.86	0.9	6	9	53	28	4
Communication	4	0.80	7.7	0	1	17	58	24
Anxiety	3	0.71	0.9	2	5	49	21	23
Positive mood	3	0.82	0	0	0	4	3	93
Liveliness	3	0.87	0	0	0	6	4	91

items had a factor loading above 0.50. All except two items had a higher corrected correlation with their own scale (item-rest-correlation) than with other scales.

The correlation coefficients between the TAPQOL scales were on average low (Table 2). Most correlation coefficients between scales were below 0.40. The correlation between the anxiety scale and the communication scale was the highest, i.e. 0.53.

Sample 2

Respondents

Response rate in the general population sample was 60% ($n = 362$). The percentage of girls in the sample was 44%. The age of the children ranged from 10 to 60 months: 34% of the children was between 10 and 24 months old, 30% between 24

and 36 months old, 31% between 36 and 48 months old and 5% between 48 and 60 months old. The sample included 62 children with a chronic illness who had visited the doctor in the last 6 months. The majority of this group had respiratory problems like asthma (12 children), chronic bronchitis (15 children) and whooping cough (4 children). Another 13 children of this group suffered from allergy problems.

Distribution and reliability

The categorised percentile distributions presented in Table 3 shows that the scores on the TAPQOL scales were skewed. The percentage of missing was low: <5% for all scales. For the general population, Cronbach's α ranged from 0.43 to 0.84 (Table 3). For most scales, the Cronbach's α was above 0.60. However, for the scales measuring

Table 2. Inter scale correlations (Spearman) of the TAPQOL scales for the preterm children sample ($n = 109$)

Scale	1	2	3	4	5	6	7	8	9	10	11
Sleeping	–										
Appetite	0.25	–									
Lungs	0.22	0.19	–								
Stomach	0.35	0.31	0.23	–							
Skin	0.06	0.19	0.08	0.06	–						
Motor functioning	0.02	0.19	0.14	0.15	0.05	–					
Social functioning	–0.03	–0.09	0.09	0.12	0.06	0.24	–				
Problem behaviour	0.25	0.14	0.10	0.30	0.18	–0.05	0.27	–			
Communication	0.25	0.45	0.30	0.32	0.18	0.16	0.15	0.30	–		
Anxiety	0.30	0.12	0.13	0.20	0.13	0.21	0.28	0.47	0.53	–	
Positive mood	0.02	0.04	0.15	0.24	0.04	0.25	0.29	0.25	0.15	0.30	–
Liveliness	–0.04	0.06	0.09	0.01	–0.03	0.17	0.41	0.09	0.12	0.22	0.31

Table 3. Cronbach's α and categorised percentual distribution of the TAPQOL scales for the general population sample ($n = 340$)

Scale	Number of items	Cronbach's α	Missing (%)	Categorised percentual distribution Scale: 0–100				
				0–24	25–49	50–74	75–99	100
Sleeping	4	0.84	0.3	0	3	18	51	28
Appetite	3	0.76	0.3	0	1	8	64	27
Lungs	3	0.84	0.3	1	1	8	9	81
Stomach	3	0.51	0.6	0	1	9	25	69
Skin	3	0.59	0.3	0	0	5	47	48
Motor functioning	4	0.43	2.4	0	0	0	12	88
Social functioning	3	0.68	1.7	1	1	10	20	68
Problem behaviour	7	0.75	0	1	7	61	29	2
Communication	4	0.69	4.2	0	0	3	51	46
Anxiety	3	0.63	0	0	1	47	21	32
Positive mood	3	0.77	0	0	0	3	2	95
Liveliness	3	0.75	0.3	0	0	3	4	93

Table 4. Interscale correlations (Spearman) of the TAPQOL scales for the general population sample (n = 340)

Scale	1	2	3	4	5	6	7	8	9	10	11
Sleeping	–										
Appetite	0.19	–									
Lungs	0.09	0.12	–								
Stomach	0.12	0.21	0.07	–							
Skin	0.08	0.09	0.03	0.06	–						
Motor functioning	0.14	0.01	–0.02	–0.15	0.05	–					
Social functioning	0.09	0.04	0.06	0.02	0.04	0.10	–				
Problem behaviour	0.20	0.19	–0.04	0.14	0.03	0.01	0.00	–			
Communication	0.11	0.07	0.08	–0.04	–0.04	0.14	0.21	0.15	–		
Anxiety	0.28	0.25	0.09	0.25	0.09	–0.04	0.11	0.44	0.15	–	
Positive mood	0.13	0.06	0.17	0.03	0.09	0.04	0.19	0.20	0.12	0.20	–
Liveliness	–0.04	0.02	0.10	–0.06	0.00	0.05	0.08	0.07	0.10	0.07	0.17

stomach problems, skin problems and motor functioning, the Cronbach's α was low.

Construct validity

HOMALS indicated that the category quantifications for 38 out of the 43 items did not violate the assumed ordinality when categories with a frequency of 10 or more were taken into account. For the six items that violated the assumed ordinality, the violations concerned small differences between two categories.

For each set of items in a scale, a separate principal component analysis was performed. All these analyses resulted in only one factor being extracted indicating the unidimensionality of the scales. All items had a factor loading higher than 0.50. All except two items had a higher corrected correlation with their own scale (item-rest correlation) than with other scales.

The correlation coefficients between the TAPQOL scales were on average low (Table 4). Most correlation coefficients between scales were below 0.30. The correlation between the anxiety scale and the problem behaviour scale was the highest, i.e. 0.44.

The validity of the distinction between health status problems and the (negative) impact on well-being of such problems was evaluated by calculating the total number of health status problems and the percentage of such problems that led to a negative feeling for the child.

Table 5 shows that the number of problems in Health Status that elicited a negative feeling in the child varied greatly among the different scales. For example, sleeping, lung and stomach problems

elicited much more negative feelings in the child than skin problems or problems with motor functioning did.

Concurrent validity

The relationships between the TAPQOL scale scores and the FS-II(R) score were calculated by means of Spearman's correlation coefficients. These correlation coefficients are presented in Table 6.

The relationships between the TAPQOL scales and the FS-II(R) score are low. This is the case for both the preterm children sample and the general

Table 5. Total number of problems and number of problems that elicited a negative emotion in the child. Both samples together (n = 449)

Scale ^a	Number of items	Total number of problems (n = 449)	Number of problems that elicited a negative emotion in the child
Sleeping	4	861	418 (49%)
Appetite	3	703	107 (15%)
Lungs	3	215	173 (80%)
Stomach	3	253	214 (85%)
Skin	3	389	70 (18%)
Motor functioning	4	438 ^b	58 (13%)
Communication	4	152 ^b	40 (26%)
Total	24	3011	1080 (36%)

^aThe scales liveliness, positive mood, problem behaviour, anxiety and social functioning are not presented because for the items in these scales there was no distinction between health status and negative emotions elicited by problems in health status.

^bScales only for children of 1.5 years and older (n = 354).

Table 6. Spearman's correlation coefficients between TAPQOL scales and the FS-II(R), for children from both the preterm sample and the general population sample (n = 449)

TAPQOL scale	FS-II(R)-score	
	Preterm children	General population children
Sleeping	0.40	0.38
Appetite	0.40	0.30
Lungs	0.13	0.19
Stomach	0.40	0.16
Skin	0.01	0.11
Motor functioning	0.15	0.03
Social functioning	0.11	0.17
Problem behaviour	0.29	0.40
Communication	0.45	0.15
Anxiety	0.42	0.32
Positive mood	0.25	0.23
Liveliness	0.28	0.16

population sample. When only the health status part of the TAPQOL scales is compared with the FS-II(R) score, the correlation coefficients are not substantially higher. However, correlation coefficients between the total TAPQOL score (all 12 scales added up) and the FS-II(R) are higher: 0.52 for the preterm sample and 0.54 for the general population sample.

Criterion validity

Criterion validity of the TAPQOL was evaluated by comparing the TAPQOL scale scores of a

group of less healthy children with those for healthy children by means of *T*-tests. Because the data were skewed we also performed the analyses with a non-parametric test, i.e. the Mann–Whitney *U*-test. The results and significance levels of these analyses did not differ substantially from the *T*-test analyses.

Firstly, preterm children with a gestational age of less than 32 weeks from the preterm children sample were compared with healthy children from the general population sample. Secondly, chronically ill children from the general population sample (mostly children with respiratory problems) were compared to the group of healthy children from the general population sample. The TAPQOL scale scores for each group are presented in Table 7.

Table 7 shows that preterm children and children with a chronic disease had significantly lower scores on several of the TAPQOL scales, indicating a worse quality of life. Almost all scales – except the scales problem behaviour, positive mood and liveliness – were significantly related to at least one of the criteria (being chronically ill or preterm born); these scales differentiated between a healthy and a less healthy group of children.

Parents were asked how healthy and how happy their child was. On the basis of these two questions, the healthy children were compared to the

Table 7. Mean TAPQOL scale scores for healthy, preterm (gestational age < 32 weeks) and chronically ill children, standard deviation (SD) and *p*-value of *T*-test of for differences of means (*p*). Higher scores indicate better HRQoL

Scale	Children			Significance (<i>p</i>)	
	Healthy (n = 251)	Preterm (n = 65)	Chronically ill (n = 62)	Healthy vs. preterm children	Healthy vs. chronically ill children
Sleeping	83.1 (±17)	75.9 (±21)	77.2 (±19)	0.004	0.018
Appetite	85.9 (±12)	82.6 (±17)	79.6 (±16)	NS	0.001
Lungs	97.2 (±9)	85.3 (±20)	78.1 (±28)	< 0.000	< 0.000
Stomach	92.6 (±13)	84.2 (±21)	87.6 (±17)	< 0.000	0.013
Skin	92.8 (±10)	90.5 (±15)	88.0 (±13)	NS	0.002
Motor functioning	98.8 (±4)	90.2 (±13)	98.0 (±5)	< 0.000	NS
Social functioning	91.4 (±15)	83.7 (±22)	90.0 (±18)	0.003	NS
Problem behaviour	67.7 (±15)	63.7 (±21)	67.0 (±16)	NS	NS
Communication	91.7 (±10)	80.9 (±15)	92.1 (±11)	< 0.000	NS
Anxiety	79.2 (±17)	66.9 (±22)	75.8 (±19)	< 0.000	NS
Positive mood	98.9 (±6)	98.4 (±6)	97.8 (±9)	NS	NS
Liveliness	98.1 (±8)	96.4 (±12)	97.0 (±10)	NS	NS

NS – not significant (*p* > 0.05).

Table 8. Mean TAPQOL scale scores for healthy, less healthy, happy and less happy children, standard deviation (SD) and *p*-value of *T*-test of for differences of means (*p*). Higher scores indicate better HRQoL

Scale	Children				Significance (<i>p</i>)	
	Healthy (n = 285)	Less healthy (n = 160)	Happy (n = 339)	Less happy (n = 107)	Healthy vs. less healthy children	Happy vs. less happy children
Sleeping	84.0 (± 16)	76.7 (± 20)	83.4 (± 17)	75.1 (± 21)	< 0.000	< 0.000
Appetite	87.6 (± 11)	89.0 (± 16)	85.7 (± 13)	80.5 (± 15)	< 0.000	0.001
Lungs	96.9 (± 9)	82.8 (± 23)	94.0 (± 15)	85.1 (± 23)	< 0.000	< 0.000
Stomach	92.6 (± 13)	84.2 (± 21)	92.6 (± 13)	87.6 (± 17)	< 0.000	0.013
Skin	92.5 (± 10)	89.3 (± 13)	92.2 (± 10)	88.4 (± 13)	0.005	0.016
Motor functioning	98.1 (± 4)	95.8 (± 13)	97.5 (± 7)	96.3 (± 8)	0.009	NS
Social functioning	91.9 (± 15)	88.0 (± 19)	91.5 (± 15)	86.6 (± 20)	0.027	0.032
Problem behaviour	68.2 (± 16)	64.3 (± 18)	70.0 (± 15)	56.6 (± 18)	0.019	< 0.000
Communication	91.6 (± 10)	87.4 (± 13)	92.3 (± 9)	82.9 (± 15)	0.002	< 0.000
Anxiety	79.0 (± 18)	72.6 (± 21)	80.7 (± 17)	63.7 (± 20)	0.001	< 0.000
Positive mood	99.4 (± 5)	97.1 (± 9)	99.6 (± 3)	95.3 (± 12)	0.006	0.001
Liveliness	98.5 (± 6)	96.3 (± 12)	98.8 (± 6)	94.3 (± 14)	0.014	< 0.000

NS – not significant ($p > 0.05$).

less healthy children and the happy children were compared to the less happy children. The TAPQOL scale scores for each group are presented in Table 8.

Table 8 shows that less healthy children had significantly lower scores on all of the TAPQOL scales, indicating a worse quality of life. Table 8 also shows that less happy children have significantly lower scores on 11 of the 12 TAPQOL scales. Particularly on the ‘problem behaviour’ and ‘anxiety’ scales, these children have much lower scores than the happy children.

Discussion

The aim of this study was to evaluate the psychometric performance and validity of the TAPQOL, a recently developed generic HRQoL instrument for 1–5-year-old children. In this study, a sample of preterm children and a sample of children from the general population were used to evaluate the psychometric performance of the TAPQOL. Because the TAPQOL-scales were constructed on the data of the preterm sample, the psychometric performance of the scales is more optimal for this sample than for other samples.

The reliability of most TAPQOL scales was good in the preterm children sample, with Cron-

bach’s α ranging from 0.66 to 0.89. Reliability in the general population sample was satisfactory for most scales. However, the Cronbach’s α for the scales relating to ‘stomach functioning’ and ‘motor functioning’ were low. This low reliability may have been due to the low prevalence and variance of problems in the general population sample. This explanation gains plausibility if the psychometric performance of the TAPQOL scales in the preterm children sample is taken into account. The prevalence and variance of problems in this group is higher, and the reliability of the scales is better. More research has to be done to evaluate the reliability of the TAPQOL scales in different samples of children with chronic illnesses. The unidimensionality of the TAPQOL scales was confirmed by principal component analysis. Almost every item-rest correlation (the correlation with its own scale) was higher than the item correlation with other scales. This also supported the scale structure.

The correlations between the scales were low, confirming the multi-dimensional definition of HRQoL. This is in accordance with the conventional approach to HRQoL as a multi-dimensional construct [5, 23]. This approach has been confirmed by psychometric evaluations of HRQoL instruments for adolescents and adults [24–28]. The results of our study show that the multi-dimensional approach of HRQoL is also valid for

very young children. This approach means that the TAPQOL is useful for measuring a broad scope of different domains. This broad scope of the TAPQOL may be helpful in measuring the impact of disease and treatment on the lives of young children, especially because it is not always clear which domains will be afflicted by disease or treatment.

Concurrent validity was evaluated by relating the TAPQOL scales with the FS-II(R) score. The correlation coefficients between the individual TAPQOL scales and the FS-II(R) were low. The absence of high correlation coefficients could be due to the different concepts that are measured: the FS-II(R) measures health status [1, 2] and the TAPQOL assesses functional problems in health status weighted by the degree to which the child shows negative emotions in relation to such problems. However, the correlation coefficients were not substantially higher when only the functional status part of the TAPQOL was compared with the FS-II(R). Another explanation might be that the TAPQOL measures 12 different scales which, on their own, have no high correlation with the 'general health' measured by the FS-II(R). This is confirmed by the higher correlation coefficient (0.54) between the total TAPQOL-score and the FS-II(R) for the general population. Use of the FS-II(R) for concurrent validity has the limitations that one parental measure is used against another, which can contribute to a higher correlation coefficient. In our study no objective assessment, for example the Bayley Scales of Infant Development [29], as measure for concurrent validity was used. Two studies are currently being undertaken in which both the TAPQOL and the Bayley-scales are used as outcome measures. Future analyses of these data can give more insight in the concurrent validity of the TAPQOL.

The assumption that a complaint or limitation in health status does not automatically lead to a negative feeling, as suggested in the literature [15–17], is confirmed by the results of our study. Only 36% of the problems in health status elicit a negative feeling in the child. This percentage varies greatly among the different scales. For example,

only 15% of the problems in the 'appetite scale' lead to a negative feeling in the child, while this figure is 85% for the 'stomach functioning scale'. These results indicate the different impact that problems in health status can have on the child's quality of life. It confirms the relevance of the distinction between health status problems and the impact of these problems on well-being. Not every problem in health status automatically triggers a bad feeling in the child. Such information may be of great value when the TAPQOL is used to evaluate different therapies or medical interventions for children. Curing health problems is not always possible in such conditions as diabetes mellitus or congenital heart disease, but a negative impact on well-being resulting from these conditions may be prevented or reduced [28]. Future studies have to show if the TAPQOL is sensitive to measure a change in HRQoL over time, and can be used to evaluate medical interventions who aim to improve children's HRQoL.

Evaluation of the criterion validity of two other HRQoL instruments for children, the FS-II(R) and the RAND, show that these two instruments distinguish between well and ill children [1, 2]. In our study, criterion validity was evaluated by relating four criteria to the TAPQOL scales. For these criteria, the group with the less good health (i.e. the preterm children and the group with a chronic illness) had a significantly lower score on most of the TAPQOL scales. These results demonstrate that the TAPQOL scales can detect differences between healthy and less healthy children.

In conclusion, the results of this study show that the TAPQOL has both good validity and psychometric performance for the preterm children sample. The psychometric performance of some scales is less satisfying in the general population sample, which might be due to the low prevalence of health status problems in this group. More research must be done to evaluate the psychometric performance of the TAPQOL in other clinical populations. The instrument may be used to assess group differences in preschool children's HRQoL, for example, in studies evaluating the effects of different treatments.

Appendix A

Items of the TNO-AZL Preschool Children Quality of Life (TAPQOL) questionnaire

Scale	Items
Sleeping	
How did your child sleep...	(1) Did your child sleep restlessly (2) Was your child awake at night (3) Did your child cry at night (4) Did your child have difficulty sleeping through the night
Appetite	
How did your child eat and drink...	(5) Was your child's appetite poor (6) Did your child have difficulty eating enough (7) Did your child refuse to eat
Lungs	
Has your child had.../Has your child been...	(8) Bronchitis (9) Difficulty with breathing or lung problems (10) Short of breath
Stomach	
Has your child had.../Has your child been...	(11) Stomach ache or abdominal pain (12) Colic (13) Nauseous
Skin	
Has your child had...	(14) Eczema (15) Itchiness (16) Dry skin
Motor functioning	
Did your child have...	(17) Difficulty with walking (18) Difficulty with running (19) Difficulty with walking up stairs without help (20) Difficulty with balance
Social functioning	
How was your child's behaviour with other children...	(21) My child was able to play happily with other children (22) My child was at ease with other children (23) My child was confident with other children
Problem behaviour	
Your child's behaviour...	(24) My child was short-tempered (25) My child was aggressive (26) My child was irritable (27) My child was angry (28) My child was restless or impatient with me (29) My child was defiant/awkward with me (30) I could not manage my child
Communication	
Did your child have...	(31) Difficulty in understanding what others said (32) Difficulty in talking clearly (33) Difficulty in saying what he/she meant (34) Difficulty in making it clear what he/she wanted
Anxiety	
How was your child...	(35) Frightened (36) Tense (37) Anxious
Positive mood	
How was your child...	(38) In good spirits (39) Cheerful (40) Happy
Liveliness	
How was your child...	(41) Energetic (42) Active (43) Lively

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