

# **The ConQol Manual**

## **A disease-specific measure of health-related quality of life for children with congenital heart conditions**

**Susan Macran\*   Yvonne Birks\*\*  
Bob Lewin\*\*   Geoff Hardman\***

\*Centre for Health Economics, University of York

\*\*Department of Health Sciences, University of York

**British Heart Foundation Care and Education Research Group  
Department of Health Sciences  
University of York**



## Acknowledgements

We would like to thank:

- the members of the Project Steering Committee and the other experts listed below who so generously gave of their time and expertise;
- Prof Robert Anderson, Mrs Wilma Dickson, Miss Carin van Doorn, Mrs H. Greig-Midlane, Mr Leslie Hamilton, Dr Barry Keeton, Mrs Lynne Kendall, Mr Paul Kind, Dr Jonathan Parsons, Professor Patricia Sloper, Dr Sara Matley, Mrs Jo Quirk;
- The staff in the following paediatric cardiology departments who helped with the national survey:  
Freeman Hospital, Newcastle; Leeds General Infirmary; Alder Hey Hospital, Liverpool; Great Ormond Street Hospital, London; Southampton General Hospital and Yorkhill Hospital, Glasgow. Particular thanks go to: Kath Ashcroft, Chris Daniels, Judith Gallagher, Amanda Haworth, Dr Alan Houston, Paul Jennings, Dr Ed Ladusans, Lorraine Leaske, Dr John O'Sullivan & Valerie Sutherland.
- All of the children and young people and their parents who helped us in this project.

The research was funded by a grant from the British Heart Foundation.

Further copies of the questionnaire, this manual, the user's manual and the scoring spreadsheet can be downloaded from [www.cardiacrehabilitation.org.uk](http://www.cardiacrehabilitation.org.uk)

If you wish to know more, or to comment on this report please contact:

Dr Y. Birks (yfb1@york.ac.uk)

BHF Care and Education Research Group

Seebohm Rowntree Building

University of York

YO10 5DD

Wednesday, 27 October 2004

## Introduction to the measure

The Congenital Heart Disease Quality of Life Questionnaire (ConQoL) was developed to provide a means of assessing a child's or young person's self-perceived health-related quality of life (HRQOL), for research or audit, or in clinic to determine where help may be required.

The ConQoL:

- is disease-specific to congenital heart disease
- is acceptable to, and well completed by children
- is valid and reliable
- is child-centred in that, unlike similar measures, it was developed from interviews with children and young people rather than the opinions of experts or parents
- asks about the *impact* of events or symptoms rather than simply listing their frequency. An event may happen frequently but not be regarded by the child as affecting their HRQOL
- ascribes child-derived weights to each item rather than a simplistic summing of item scores. Weightings were also obtained from clinicians and parents and are presented here for researchers who may wish to use them
- is age-specific: the interviews revealed that at around the age of 12, children's perception of the things that matter to them change. Thus the ConQoL is in two forms, one for children from 8–11 years the other from 12–16 years
- has a separate symptom score, symptoms may be reported by children but not viewed by them as being important. In the interviews, symptoms were rarely mentioned as problematic. Clinicians on the steering committee for the development of the measure felt that despite this, symptom reports provide important information. This information is therefore gathered but scored separately.

The ConQoL produces three measures:

1. a *quality of life index score* based on questions about activities, relationships, coping and control
2. a *descriptive profile of the frequency symptoms* experienced by the child in the past week
3. a weighted *symptom index score* summarising how difficult these symptoms had made respondents lives.

The development of the ConQol was in four main steps:

1. interviewing children to ascertain their views about their quality of life
2. constructing a first version and piloting it in Yorkshire
3. determining the weighting and scoring systems
4. developing the final version and conducting a national survey from five paediatric cardiology centres using the ConQol, alongside two other HRQOL measures, to establish its validity and reliability and gather some national norms.

## **Step 1: qualitative research with children**

### *1.1 The interviews*

Children attending outpatient clinics of the Yorkshire Heart Centre were invited to take part, subject to the following exclusions:

- a normal heart or innocent murmur
- younger than 8 years of age
- neurological problems which make communication difficult
- less than two months since surgery
- unable to speak English.

Sampling was subject to monitoring to ensure that a representative group of children and young people were interviewed. The sampling frame included age, gender and complexity of the underlying problem/prognosis. Recruitment continued until no new themes were arising in the interviews. Children were interviewed in their own homes, whenever possible with their parent not present in the same room (or when they were, the parents were asked not to answer for the child). Interviews were taped and transcribed.

Of the 38 interviews arranged, one child was not at home at the time of the interview, one was not transcribed, as the child's speech and cognitive function were of a level that made the interview technique inappropriate for them, and one interview was lost due to equipment failure. Thus 35 interviews were available for analysis.

Interviews were loosely structured around a topic guide developed from the previous literature and from feedback from the project steering committee. As new topic areas were introduced by the children these topics were added.

The transcripts were analysed using the 'framework method' (Richie and Spencer, 1994). This process involves a number of stages:

- familiarisation with the data
- identifying the thematic framework from both a priori areas of the topic guide as well as emergent issues from the transcripts
- indexing the framework against transcripts
- charting the data systematically

- finally, interpreting the data by tracing patterns and associations to identify the overarching themes.

## 1.2 Results of the interviews

Six main themes emerged from the analysis.

*Physical effects:* physical sequelae included breathlessness, tiredness, chest and leg pain, dizziness and fainting, changes in skin colour and scarring.

*Restrictions on activity:* these might be imposed by the child themselves or by others. School sports were a particularly common area of difficulty.

*Attitudes of others:* this was the most frequently described problem and made a huge difference in how the children coped with their condition.

*Choices about information:* who knew about their condition and how this information is given out was very important to the children.

*Coping with life:* general strategies that they used to manage on a day-to-day basis.

*Privacy:* feelings of being stifled by the attention that their condition required or, mainly for older children, being physically examined.

A short age-appropriate summary of these findings was sent to the children to check that the investigators had properly represented their views. All of the interviewees were happy with the accuracy of the report.

## Step 2. Constructing and piloting the measure

### 2.1 Generating the items from the themes and interviews

For a measure to have good content validity, each item should relate to the objectives of the measure and each objective of the measure should be represented by at least one question. Two members of the ConQol team (YB and SM) generated potential questionnaire items for each of the themes using the children's own language, taken from the interview transcripts. The goal was to ensure that the measure had enough items to cover adequately the theme under investigation.

A list of 50 possible items was produced grouped into six dimensions. These differed slightly from the six original themes, but were felt to be more pertinent to an outcome measure. They were:

*Physical symptoms* such as, breathlessness, tiredness, aches and pains.

*Mood and cognition* – items about forgetfulness, sadness, anxiety, feeling different.

*Ability to do activities* – physical and social.

*Relationships with others* – friendships, bullying, expectations of others.

*Control over health/body* – feeling involved in decisions about their health and having control over their body.

*Coping with illness* – how much they think about their heart and their health.

The list was circulated to the expert steering group for discussion and comment. Some were discarded as unsuitable or potentially ambiguous and it was decided to group those items in the 'physical symptoms' dimension and 'mood and cognition' dimensions together to form a single 'symptoms' dimension. Similarly, items in the 'control over health/body' dimension and the 'coping with illness' dimension were also grouped together to form a 'control and coping' dimension.

## *2.2 Choosing a method for scaling the item responses*

The choice of method for obtaining a response to an item is dictated by the nature of the question. Some items fit a simple bivariate 'either/or' response but those that measure the magnitude of a respondent's feelings or attitudes require a continuous scale to record the degrees of agreement or disagreement. As we aimed to measure the extent to which the children felt their heart disease affected the different aspects of their life it was clear that we needed to use the continuum approach. To do this, a visual analogue scale (VAS) method was chosen whereby respondents place a mark on a line that has designated anchor points, choosing the point that best represents their feelings.

A 0 to 10, horizontal, visual analogue scale (VAS) was used. The anchor points differed according to the dimension: thus items in the *symptoms* dimension were measured on a, 0 = 'not at all difficult' to 10 = 'really difficult' scale; in the *activities* dimension the anchors were 0 = 'as much as I want to' to 10 = 'not as much as I want to'. The remaining dimensions had anchor points of 0 = 'all of the time' to 10 = 'none of the time'. For all items the direction of the visual analogue scale was the same: 0 = positive and 10 = negative, thus the higher the score the worse the HRQOL.

## *2.3 Recording the frequency of symptoms*

The steering committee felt that asking about the frequency with which each symptom was experienced would be useful for clinical purposes. Thus, in addition to completing a VAS for each item, respondents were also asked to indicate how often they had experienced a symptom on a four-category response scale: 'not at all', 'a few days', 'most days', 'every day'.

## *2.4 Choosing a recall period*

In deciding on the recall period for an outcome measure, a trade-off has to be made between defining a period long enough to give the opportunity for an event to occur and one that is too long for respondents to recall events accurately. A recall period of one week was chosen, as it was felt that younger children would struggle to recall their behaviour or feelings over a longer time period.

## *2.5 Creating age-appropriate versions*

The interviews revealed that the concerns of older and younger children differed. In particular, older children were more likely to talk about problems with coping and control. Two versions of the questionnaire were developed, one for the 8–11-year age group the other for the 12–18 year age group. This also reflected the transition point from primary to secondary school.

The younger children's scale contained 31 items grouped into three dimensions:

- symptoms
- ability to do activities
- relationships with others.

The 12–18-year-old version included an extra dimension relating to locus of control/coping and contained 39 items.

The wording for items that were common across the two versions was identical. The anchor points on the visual analogue scales for the 8–11 version were illustrated using sad and happy faces to indicate the direction of the scale.

## *2.6 Piloting the initial version of the measure*

Copies of the initial questionnaire were distributed to 320 children with congenital heart disease, recruited either from a random sample from the clinic lists at Leeds or from all those attending clinic during a one-week period in March. A control sample of 60 children was recruited from primary and secondary schools in York.

The children received an age-appropriate information form, a parental information form, a consent form, questionnaire and a prepaid return envelope. All children were offered a £5 gift voucher for returning a completed questionnaire. Responses were received from 73 8–11 year olds and 98 12–18 year olds.

## *2.7 Changes to the measure resulting from the pilot study*

The psychometric performance of the measure was scrutinised in terms of its coverage, endorsement frequency and dimension structure.

Data were analysed for the younger and older age groups separately. Analysis revealed that the questionnaire appeared to be acceptable to both younger and older children, with low levels of missing data. Some of the symptoms items had relatively low endorsement frequencies for both younger and older children, however the decision was made to retain them for completeness of coverage.

Hierarchical cluster analysis revealed that for both groups of children the activities items clustered together and the relationships items clustered together. For the older children the coping and control items did not form a distinct grouping but tended to cluster with the relationships items.

The intention was to keep as many common items as possible across the two age versions. However analysis showed that some could be dropped. For example, an item referring to going to town shopping with friends in the 8–11 version had a

relatively high number of missing responses and cluster analysis revealed that it did not cluster with any of the other items. Other items were dropped because they had similar wordings and correlated highly. The wording on some items was changed slightly, mainly to ensure that a consistent but also age-appropriate wording could be used across the younger and older versions.

It was decided to reduce the upper age limit of the older version from 18 years to 16 years as many of the 18 year olds had left school and were working or facing a different set of challenges; a number of the items were irrelevant and other important ones were not recorded.

As the recall period of the measure was restricted to one week, it was considered appropriate to add a 'not applicable' category to the 'being able to go to clubs or activities outside of school' item. This was to cover instances when a respondent may not have had the opportunity to participate in that activity.

An extra item was added to both versions, asking the child to indicate how they have felt in the past week compared to how they feel most of the time. This is also scored using a 0 to 10 visual analogue scale with anchor points of 'much better than usual' and 'much worse than usual'. This item is of use to clinicians to determine whether this is a persistent problem or whether there has been some particular upheaval in the previous week that may represent a transitory state.

### *2.8 The final version of the measure*

Thus the final ConQol consists of two age-appropriate versions, 8–11 years and 12–16 years. These are attached as an appendix.

The 8–11-year version consists of 29 items that cover three dimensions: symptoms (13 items), activities (6 items) and relationships (10 items). The 12–16-year version consists of 35 items covering four dimensions: symptoms (13 items), activities (7 items), relationships (10 items) and control and coping (5 items).

## **Step 3. Determining the weighting and scoring system**

### *3.1 Generating a single index number using weighting*

The ConQol has been designed to produce two weighted index scores:

- a weighted *symptom index score* summarising how difficult the experience of their symptoms had made respondents' lives
- a *quality of life index score* based on responses to the activities, relationships and coping and control items.

These scores involve combining individual items to form a single index *score*. This clearly involves a loss of descriptive information but does not prevent clinicians from reading the completed questionnaire to determine where the child or young person

has indicated specific problems. For research and audit studies it has the advantage over using a profile of scores that it can be used as a single measure in statistical analyses to record change in the overall quality of life or symptom load over time.

The simplest way to generate an index score is to add up the raw scores on each item. However this method makes the assumption that all of the items in the measure are equally important. It disregards the possibility that some items may be more important than others and therefore should make a correspondingly larger impact on the final score.

A more sophisticated method is to develop a scoring system which *weights* each item differently in terms of its contribution to the total score. The decision to adopt this approach raises the question of how those weights should be generated. Options include taking some sort of theoretically based approach and asking the instrument developers or respondents about which items they think are most important with respect to the underlying attribute being measured (i.e. health-related quality of life) or a more empirical approach using one of the psychometric techniques, which have been used to generate values for health states, or a combination of the two methods. The choice is determined partly by theoretical orientation and partly by the purposes for which the measure is to be used.

The intention in developing the ConQol has been to use a bottom-up approach in which its content has been derived from those topics that children consider to be important. Therefore it was deemed most appropriate to obtain weights from a sample of children and for these weights to be elicited in an empirical fashion. It was also agreed that weights would be gathered from a sample of clinicians and parents of children with congenital heart disease.

### *3.2 The weighting exercise*

#### *Children and parents*

Weighting questionnaires were sent to 120 children and their parents in the older age group (12 and above) who had returned their questionnaire; a response of 82 children (a 68% response rate) and 78 parents (a 65% response rate). A control group of 45 children with no cardiac condition were also asked to complete the questionnaire; 38 responses were returned (a response rate of 84%).

#### *Health professionals*

Questionnaires were distributed to 70 health professionals; 33 were returned (a 47% response rate).

#### *Weighting questionnaire*

Respondents were asked to give each item of the ConQol a score from 0 to 10 where 10 equals 'very important for quality of life' and 0 equals 'no importance for quality of life'. Respondents were asked to imagine a child aged between 8–16 years with a heart problem and to think about how important each item would be for that child's quality of life (if he or she had it for one week and experienced that item either 'all the time' or were not able to do it 'as much as they wanted to', whichever was the worst response category for that item).

Instructions differed slightly in the questionnaires sent to children, clinicians and parents. Children with a heart problem were told that they could think about themselves if they wanted to. They were asked whether they had thought about themselves, someone else or an imaginary person; 65% said they thought of themselves.

The sample of clinicians was also asked to score the 13 symptom items in a similar fashion on a 0–10 VAS. In this case they were told to assume that each symptom had been making the child's life really difficult for a week.

### 3.3 Results of the weighting exercise

#### *Quality of life items*

Table 1 presents the mean weights for the items for each of the four respondent groups.

The item that received the highest weight was 'being able to spend time with friends' (mean 8.44, SD 2.1), the lowest was 'get fed up with telling people about my health' (mean 6.97, SD 2.3).

Overall there was very little variability in the weights for the different items; most tended to fall between 7 and 8.

Clinicians tended to have a narrower range of scores than the other three groups and to show more agreement in the score they give to a particular item.

Comparing across the groups the mean values for all of the items tended to show a similar pattern. The clinicians tended to give items the highest weights and children with congenital heart disease tended to give items the lowest weights. Significant differences in the mean weights across the four respondent groups were observed for four items:

- unable to go to clubs
- unable to go to town
- unable to do the things friends do
- people fussing too much.

Although the mean scores were not different, there were differences in the rank order of the means across the four groups. A Kruskal-Wallis test revealed the ordinal structure to be significantly different ( $P < 0.001$ ). On the whole, both groups of children tended to give higher weights (i.e. more impact on quality of life) to the relationships items than the activities items, while parents and clinicians gave slightly higher weights to the relationships items. Children with no CHD also gave high scores to the control and coping items.

Table 1. Weightings from children, parents and clinicians

	Children with CHD		Parents		Children - no CHD		Clinicians		All	
	Mean (rank)	SD	Mean (rank)	SD	Mean (rank)	SD	Mean (rank)	SD	Mean (rank)	SD
<b>Activities</b>										
Able to run about	7.23 (14)	2.7	7.55 (16)	2.3	6.97 (20)	2.3	8.03 (16)	1.6	7.41	2.4
Allowed to do sports and exercise	6.96 (20)	2.6	7.35 (17)	2.4	7.58 (10)	2.2	7.78 (19)	1.7	7.31	2.4
Able to spend time with friends	8.29 (2)	2.2	8.55 (1)	2.1	7.92 (8)	2.5	9.16 (1)	1.2	8.44	2.1
Able to keep up with friends	7.80 (8)	1.9	8.05 (7)	1.9	7.58 (10)	2.1	8.70 (5)	1.5	7.98	1.9
Able to go to clubs/do activities outside of school	6.87 (21)	2.7	7.63 (14)	2.2	7.18 (19)	2.3	8.27 (10)	1.5	7.38	2.3
Able to go to town shopping with friends	7.13 (16)	2.5	7.58 (15)	2.3	6.45 (24)	2.4	8.09 (15)	1.6	7.31	2.4
Allowed to do things friends do	7.55 (10)	2.4	8.31 (3)	1.7	7.58 (10)	2.4	8.91 (2)	1.4	8.00	2.1
<b>Relationships</b>										
Get on well with friends	8.15 (4)	2.0	8.21 (4)	2.2	8.16 (3)	1.9	8.39 (7)	1.4	8.20	2.0
Friends look out for me	7.72 (9)	2.0	7.77(11)	2.0	8.26 (2)	1.7	8.15 (14)	1.6	7.89	1.9
Find it hard to make friends	7.99 (5)	2.0	8.08(6)	2.2	8.05 (7)	1.6	8.55 (6)	1.5	8.11	2.0
People fuss over me too much	6.12 (24)	2.3	6.63 (24)	2.2	6.95 (22)	1.9	7.33 (24)	2.1	6.60	2.2
Get picked on and teased	8.32 (1)	2.3	8.36 (2)	2.4	8.16 (3)	2.8	8.79 (4)	1.8	8.37	2.4
Feel lonely	8.18 (3)	2.4	8.18 (5)	2.8	8.08 (6)	2.7	8.82 (3)	1.4	8.26	2.5
Allowed to do things able to do	7.98 (6)	1.8	7.95 (8)	2.2	7.79 (9)	2.0	8.24 (13)	1.7	7.97	2.0
People expect me to do too much	6.98 (19)	2.2	7.10 (22)	2.3	7.29 (18)	2.2	7.61 (20)	1.6	7.16	2.2
Can do more than people think	7.21 (15)	2.1	7.28 (19)	2.3	7.39 (15)	1.9	7.36 (23)	2.0	7.29	2.1
People understand what I can manage to do	6.99 (17)	2.1	7.18 (20)	2.4	7.32 (17)	1.9	7.85 (18)	1.6	7.23	2.2
<b>Control of health/body</b>										
Feel like my body is not my own	6.99 (17)	2.9	7.33 (18)	2.6	7.50 (13)	2.3	8.33 (8)	1.7	7.38	2.6
Feel like my health is out of my hands	7.41 (11)	2.6	7.67 (12)	2.5	8.13 (5)	1.8	8.03 (16)	1.7	7.70	2.3
Fed up with telling people about health	6.54 (23)	2.6	6.99 (23)	2.5	7.37 (16)	1.8	7.55 (22)	1.8	6.97	2.3
I think about my heart	6.62 (22)	2.6	7.17 (21)	2.4	7.47 (14)	2.0	7.58 (21)	1.9	7.08	2.4
Life is good	7.87 (7)	2.6	7.87 (9)	2.6	8.32 (1)	2.0	8.27 (10)	1.7	8.00	2.4

### 3.4 Weighting of symptom items by clinicians

Table 2 presents the mean and median scores obtained for the 13 symptom items valued by the clinicians. As with the quality of life items, there was little range or variation in the weights.

Table 2. Weightings from clinicians

Item	Mean (rank)	SD
Short of breath or puffed out	9.15 (1)	1.1
Too tired	8.67 (2)	1.2
Aches and pains	8.24 (9)	1.3
Dizzy or faint	8.58 (4)	1.4
Unable to keep up with schoolwork or homework	8.12 (10)	1.6
Difficulty concentrating	8.09 (11)	1.5
Forgetful	7.73 (13)	1.7
Slowed down thoughts	7.79 (12)	1.7
Sad or fed up	8.42 (5)	1.6
Worried or nervous	8.42 (5)	1.6
Feeling different from others	8.59 (3)	1.8
Feel like treated differently from others	8.27 (8)	1.9
Uncomfortable with looks	8.28 (7)	1.8

### 3.5 The scoring method

The ConQol is scored by multiplying the score for each item by the mean weight for that item and then summing the resulting scores. Scores are calculated as a proportion of a theoretical maximum score and multiplied by 100 to conform to a 0 to 100 scale, where 0 equals worst quality of life and 100 equals best quality of life. This standardisation allows for scores from the older and younger version of the ConQol to be compared.

Some items are reverse scored (see Appendix).

Separate index scores are generated for the quality of life items (ConQol index score) and the symptom items (ConQol symptom score).

*To ease comparability across studies that use the ConQol, it is recommended that the ConQol index score is always reported.*

### 3.6 Managing missing data

Where a questionnaire has responses missing it is suggested that the ConQol index score be calculated only if there are three or less items missing. For such cases the theoretical maximum score is adjusted to take into account the items that are missing.

*These manipulations make scoring complex and prone to computational error and we strongly suggest that the Microsoft Excel spreadsheet that is supplied with the questionnaire is used to automate this task.*

For people wishing to score by hand or wishing to use the alternative weightings, the method is given in the Appendix.

### 3.7 Alternative scorings

The ConQol was developed with a child-centred philosophy and we recommend using the weights elicited from children with congenital heart disease (Table 1, column 1). These are the weights used in the Excel spreadsheet. The weights generated by other groups are shown in Table 1. These may be used if researchers have specific interests but it is important to remember that it is not legitimate to compare scores that have been calculated using one set of weights with scores that have been calculated using a different set of weights.

## Step 4. Testing the final version in a national survey to determine validity and reliability and to gather some national norms

### 4.1 The validation study method and results

Five paediatric cardiology centres agreed to mail to a sample of suitable children on their patient lists. They were: Southampton General Hospital; Freeman Hospital, Newcastle; Royal Liverpool Children's N.H.S. Trust, Great Ormond Street Hospital, London; Royal Hospital for Sick Children, Glasgow.

The same exclusion criteria were used as in the pilot study. As in the pilot study, all of the children who returned a completed questionnaire received a £5 gift voucher. In addition to the ConQol, the subjects completed the EQ-5D (EuroQol) and the PEDS-QL; these are described more fully below.

A total of 1,416 questionnaire packs were sent to children and young adults, of which 672 responses were returned (a response rate of 47%). A further 241 children were identified from the Yorkshire Heart Centre, from whom 129 responses were received (a 53% response rate). Table 3 shows the response rate by age.

Table 3. Response rate by age

Age (years)	8–11 year old sample	12–16 year old sample
8	43	
9	82	
10	76	
11	97	1 <sup>a</sup>
12	25 <sup>a</sup>	65
13		89
14		63
15		77
16		41
<b>Total</b>	<b>323</b>	<b>336</b>

<sup>a</sup> Children who have had a birthday during the sampling period

#### 4.2 ConQol index score: distribution

Figure 1 presents distribution of the ConQol index score for children aged 8–11 years. The mean was 75.0 (SD 17.6) and the median 79.5. The maximum score was 100 and the minimum was 5.6. A ConQol index score could be calculated for all 323 children in the sample.

Figure 1. Distribution of the ConQol index score: 8–11 years

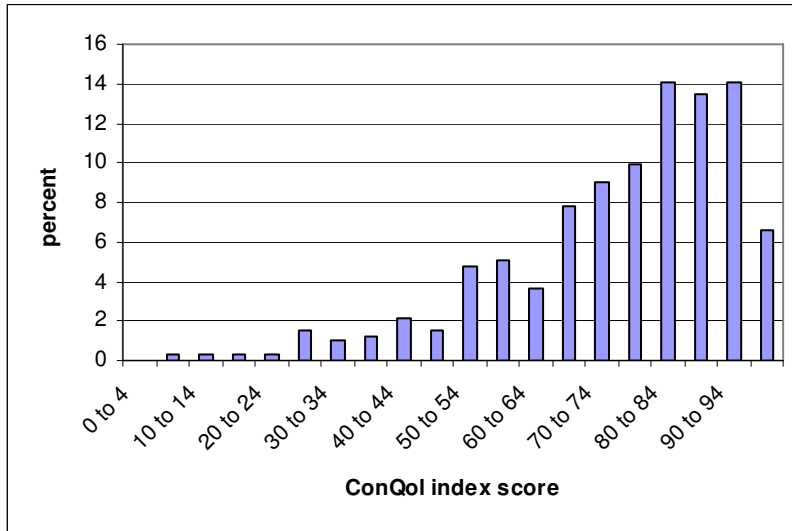
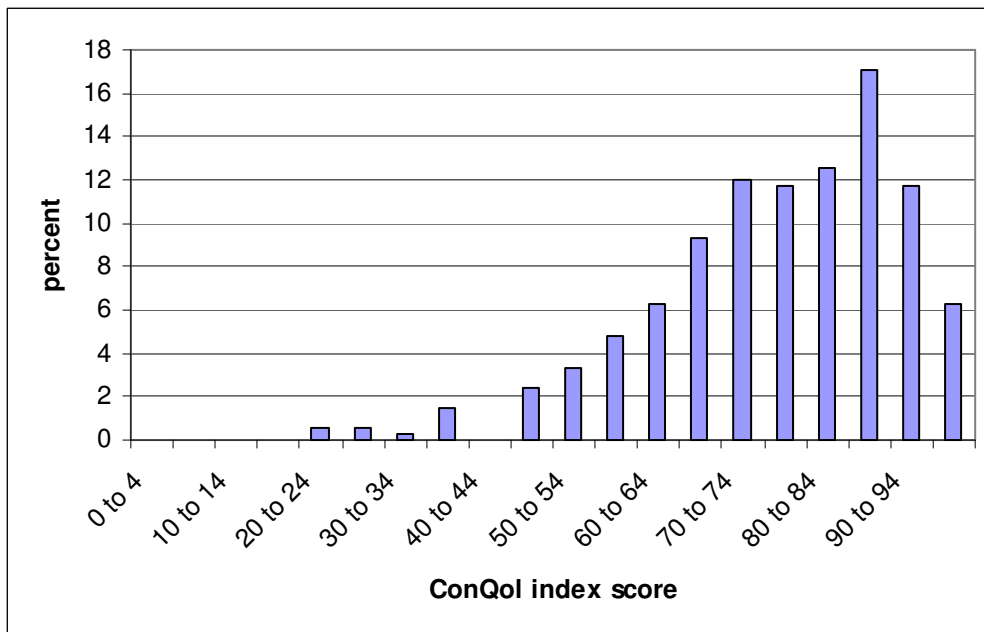


Figure 2 presents distribution for children aged 12–16 years. The mean was 76.0 (SD 14.9) and median 78.7. The maximum score was 100 and the minimum was 20.8. A score could be calculated for 335 of the 336 cases.

Figure 2. Distribution of the ConQol index score: 12–16 years



### *4.3 Missing data*

The levels of missing data in the 8–11-year-old questionnaires were low (3 or less cases per item) with one exception ‘In the past week I have been able to go to clubs/do activities outside of school’ where 37% of the sample said that they had no opportunity to take part in this activity in the last week and a further 2% failed to answer the item.

In the 12–16 year olds the level of missing data were also low (5 or less cases per item). However, 44% of the sample said that they had no opportunity to ‘go to clubs/do activities outside of school in the past week’.

### *4.4 Establishing reliability*

Health outcome measures are useful only when they can be shown to be reliable (in that they produce results which are reproducible) and valid (in that they measure that which they are intended to measure).

A reliable measure is one that measures something consistently. An assessment of the reliability of an outcome measure reflects the amount of error that is inherent in it, both random and systematic. In general a reliable measure should be homogenous, i.e. all the items should tap different aspects of the same underlying attribute (in this case, children’s health-related quality of life), and it should also show a certain degree of consistency over time, for instance when administered on two separate occasions.

### *4.5 Homogeneity*

The homogeneity of a measure can be assessed by looking at the item total correlation of a scale, which is the correlation of an individual item with the scale total, omitting that item and calculating Cronbach’s  $\alpha$ .

For both age samples, Cronbach’s  $\alpha$  for the measure was 0.86, which reflects a good level of internal consistency: an  $\alpha$  of 0.7 or above is desirable and an  $\alpha$  of higher than 0.9 suggests item redundancy.

Table 4 presents the item-total correlations (Pearson’s  $r$ ) for both samples. The usual rule is that items should have a correlation of 0.20 or above. On this basis, one item: ‘I can do more than people think’ does not perform particularly well for either age group.

Table 4. Item-total correlations

	8–11 year olds	12–16 year olds
<b>Ability to take part in activities</b>		
Able to run about	0.59	0.58
Able to do sports and exercise	0.61	0.52
Play with friends	0.65	0.56
Keep up with friends	0.65	0.65
Go to clubs	0.43	0.22
Do things friends do	0.74	0.65
Go to town or shopping with friends	n/a	0.49
<b>Relationships with others</b>		
Get on with friends	0.64	0.60
Friends look out for me	0.46	0.40
Hard to make friends	0.47	0.47
People fuss over me	0.35	0.34
Picked on and teased	0.53	0.53
Feel lonely	0.60	0.60
Allowed to do things am able to do	0.59	0.54
People understand what I can and can't do	0.55	0.39
People expect too much	0.46	0.37
Can do more than people think	0.05	0.01
Feel like body is not my own	n/a	0.55
Feel like health is out of my hands	n/a	0.46
Get fed up with telling people about health	n/a	0.40
Think about my heart	n/a	0.38
Life is good	n/a	0.53

#### 4.6 Test-retest reliability

Test-retest reliability measures the consistency of scores over time. The time interval selected is crucial. If it is too short, respondents may recall their answers from the first occasion, while if it is too long the characteristic being measured may have changed. The appropriate time interval is dependent on the characteristic being measured and as such there are not standard rules for determining its length. In this study we chose to take six weeks as a reasonable interval.

The correct coefficient used to represent this form of reliability is the intra class correlation coefficient (ICC), where a value of 0 represents no reliability and a value of 1 represents perfect reliability (i.e. no measurement error). Table 5 shows that the ConQol index score was reasonably stable over a six-week retest period, with an ICC of 0.7 or above for both age groups. Paired t-tests also indicated that the mean scores for both age groups at time 1 and time 2 were not significantly different.

Table 5. Intraclass correlations at six weeks

	8–11 yr olds (N = 43)	12–16 yr olds (N = 35)
ICC	0.73	0.69
Mean (SD) ConQol index time 1	82.1 (14.3)	79.9 (12.6)
Mean (SD) ConQol index time 2	85.0 (14.1)	80.4 (13.2)

#### 4.7 Validity

The most common method to establish the validity of a measure is by observing its association with some other criterion which is, or is believed to be valid. This might be some objectively determined characteristic, or another measure that is accepted as a 'gold standard'. However, there is no gold standard in this field by which to determine validity.

The validity of the ConQol was examined in two ways:

1. against two other previously validated measures. One a disease-specific measure: the Paediatric Quality of Life Inventory (PedsQL) with its cardiac module (Uzark *et al.*, 2003); the other a generic measure of HRQOL – a version of EQ-5D adapted for children (Hennessy and Kind, 2002);
2. through its ability to discriminate between patients grouped in terms of the severity of their disease.

##### *The PedsQL*

*The PedsQL* is an instrument for measuring health-related quality of life in children and adolescents aged 2 to 18 years, divided into three age-specific versions. It has four core dimensions (physical function, emotional function, social function, school function) designed to be applicable for all children and young people, plus a series of disease-specific, bolt-on modules, including a cardiac module consisting of six dimensions: heart problems and treatment; treatment II; physical appearance; treatment anxiety; cognitive problems; communication. Unlike the ConQol it was developed from expert suggestions not from children's own perceptions.

The versions used in this instance were the 8–12 and 13–18 versions with the cardiac module. The PedsQL items are scored on a 5-point scale from 0 = never to 4 = almost always. To calculate dimension scores, items are reverse scored and transformed to a 0–100 scale as follows: 0 = 100; 1 = 75; 2 = 50; 3 = 15; 4 = 0. 100 indicates least problems and 0 indicates most problems. The mean score of items for each dimension is then calculated. (NB the Treatment II dimension is only completed by children who are currently taking heart medicine.)

##### *The EuroQol for children*

EQ-5D is a generic measure of health status designed for use in the evaluation of health and health care of adults. It measures self-reported health in terms of five dimensions: mobility; self care; usual activities; pain/discomfort; anxiety/depression and global health. A modified version of EQ-5D, which maintains the same dimensions and the visual analogue scale but uses more 'child friendly' wording has been developed for use with children aged 8 to 18 years. The EQ-5D consists of five items corresponding to its five dimensions; children have to record their level of problems today on

each item using a 3-level scale (no problems, some problems, a lot of problems). In addition, respondents are asked to rate how good their health is today on a visual analogue scale marked 0 to 100, where 100 equals the best possible health they can imagine and 0 represents the worst possible health they can imagine. (See Table 6.)

#### 4.8 Relationship between ConQol index score and EQ-5D

For both samples, most problems were reported on the pain/discomfort and anxiety/depression dimensions. Fewest problems were reported on the self-care dimension. The mean EQ-5D vas score for the younger age group was 86.8 (SD 17.2) and 81.5 (SD 18.8) for the older age group.

Table 6. Percentage reporting EQ-5D dimensions

	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/dep
<b>8–11 year olds</b>					
No problems	85	93	77	67	71
Some problems	13	7	21	31	26
Severe problems	2	--	2	2	3
<b>12–16 year olds</b>					
No problems	87	97	79	68	72
Some problems	11	2	20	28	25
Severe problems	2	1	1	4	3

Table 7. EQ-5D dimension levels by ConQol index score, 8–11 year olds

	Mean (SD)	Ratio with level 1 (mean level x/mean level 1)	N
<b>Mobility</b>			
no problems	78.1 (15.4)	1.0	269
Some problems	61.1 (17.5)	0.78	41
Severe problems	49.7 (20.9)	0.63	7
<b>Self care</b>			
No problems	77.0 (15.8)	1.0	295
Some problems	52.5 (19.9)	0.68	22
Severe problems	--	--	--
<b>Usual activities</b>			
No problems	79.2 (15.0)	1.0	244
Some problems	63.4 (17.2)	0.81	66
Severe problems	50.4 (20.4)	0.64	7
<b>Pain/discomfort</b>			
No problems	78.3 (16.1)	1.0	213
Some problems	70.2 (17.2)	0.90	97
Severe problems	54.1 (19.4)	0.69	7
<b>Anxiety/depression</b>			
No problems	79.1(15.4)	1.0	225
Some problems	67.2 (17.7)	0.85	83
Severe problems	55.1 (17.2)	0.70	9

Increasing severity level on each EQ-5D dimension was associated with a lower (i.e. worse) ConQol index score. Calculating the ratio between the mean for a particular level with the mean for level 1 showed that there was a slightly larger decrease in ConQol index scores with increasing severity of the mobility and usual activities dimensions, compared to the pain/discomfort and anxiety/depression dimensions. (See Table 7.)

Table 8. EQ-5D dimension levels by ConQol index score, 12–16 year olds

	Mean	Ratio with level 1 (mean level x/mean level 1)	N
<b>Mobility</b>			
no problems	78.7 (12.9)	1.0	284
Some problems	63.0 (15.1)	0.80	37
Severe problems	46.8 (16.4)	0.59	6
<b>Self care</b>			
No problems	76.9 (14.1)	1.0	319
Some problems	57.9 (14.6)	0.75	7
Severe problems	23.8 (--)	0.31	1
<b>Usual activities</b>			
No problems	80.2 (12.0)	1.0	257
Some problems	62.9 (14.9)	0.78	65
Severe problems	51.4 (10.2)	0.64	5
<b>Pain/discomfort</b>			
No problems	80.8 (11.9)	1.0	223
Some problems	68.8 (13.7)	0.85	91
Severe problems	51.5 (17.1)	0.64	14
<b>Anxiety/depression</b>			
No problems	79.7 (13.1)	1.0	237
Some problems	68.8 (14.1)	0.86	81
Severe problems	55.6 (17.2)	0.68	10

Table 8 presents the same table for the 12–16 year sample. As for the younger group, ConQol index scores decreased with increasing EQ-5D severity on the EQ-5D dimensions. This was particularly marked for the self-care dimension. The relationship between ConQol index score and EQ-5D vas score was slightly stronger for children aged 12–16 than for those aged 8–11 years: Pearson's  $r = 0.43$  and  $0.56$  respectively.

#### 4.9 Relationship between ConQol index and PedsQL

Table 9 presents the scores on the PedsQL for both age groups.

Table 9. Mean scores on the PedsQL

	8–11 year olds		12–16 year olds	
	Mean (SD)	N	Mean (SD)	N
Physical function	79.5 (21.4)	312	78.8 (20.0)	328
Emotional function	74.3 (21.1)	317	76.4 (20.1)	328
Social function	81.6 (20.2)	317	81.5 (20.1)	327
School function	71.1 (20.5)	316	70.9 (20.7)	327
Heart problems + treat	72.1 (22.7)	309	71.6 (21.9)	320
Treatment II	91.6 (12.8)	80	92.2 (10.8)	102
Physical appearance	75.3 (26.7)	295	72.9 (27.1)	308
Treatment anxiety	77.2 (25.6)	309	77.9 (26.0)	317
Cognitive problems	72.3 (23.9)	308	70.2 (24.1)	322
Communication	67.6 (27.3)	313	68.7 (26.8)	326

Younger children reported lowest (worse) scores on the communications problems, school function and heart problems dimensions. For older children, lowest scores were on the communication problems, cognitive problems and school function dimensions. For both groups the highest (best) score was on the Treatment II dimension; few children reported problems on this dimension.

Table 10 shows the relationship (Pearson's  $r$ ) between the PedsQL dimension and ConQol index score as well as EQ-5D vas.

Table 10. Correlation (Pearson's  $r$ ) between the PedsQL dimension, ConQol index score and EQ-5D vas

	8–11 year olds		12–16 year olds	
	ConQol	EQ-5D vas	ConQol index	EQ-5D vas
Physical function	0.53	0.57	0.67	0.60
Emotional function	0.51	0.46	0.60	0.47
Social function	0.67	0.45	0.70	0.50
School function	0.52	0.40	0.59	0.49
Heart problems + treat	0.58	0.60	0.62	0.58
Treatment II	0.07	0.12	0.49	0.35
Physical appearance	0.39	0.26	0.44	0.41
Treatment anxiety	0.48	0.26	0.41	0.26
Cognitive problems	0.52	0.36	0.56	0.37
Communication	0.42	0.34	0.56	0.42

For both groups, ConQol index score correlated best with the core PedsQL dimensions plus the heart problems dimension. This was not unexpected as many of the PedsQL cardiac items are not covered by the ConQol, or others, such as experience of symptoms, are included in the ConQol symptom score.

For younger children, the best correlation was achieved with the social function dimension ( $r = 0.67$ ) followed by the heart problems dimension ( $r = 0.58$ ). For older children, the social function dimension also showed the best relationship with ConQol index score ( $r = 0.70$ ) followed by the Physical Function dimension ( $r = 0.67$ ). Correlation between the ConQol score and the PedsQL Treatment II dimension was particularly low for younger children; this dimension also had a poor correlation with EQ-5D vas. Correlations between PedsQL and ConQol tended to be higher for older children compared to younger children. Similarly, correlations between EQ-5D vas and PedsQL were slightly higher for the older age group.

#### 4.10 Validity: discrimination by disease severity

Two independent measures of disease/illness severity were included in the survey:

1. Children were classified according to the severity of their diagnosis using the grading suggested by the American College of Cardiology (Warnes *et al.*, 2001). This identifies three groups of the severity of the underlying cardiac conditions: great complexity, moderate complexity and simple.

2. Respondents were asked to self-report the extent to which they felt their heart condition affected their daily life on a three point scale: does not affect daily life, affects daily life a little, affects daily life a lot.

Of the 8–11 year olds 9% (N = 28) of the sample had a ConQol index score of less than 50 and 39% of these children were classified as having a heart problem of great complexity using the American College of Cardiology classification and 54% said that they felt their heart condition affected their daily life ‘a little’ or ‘a lot’.

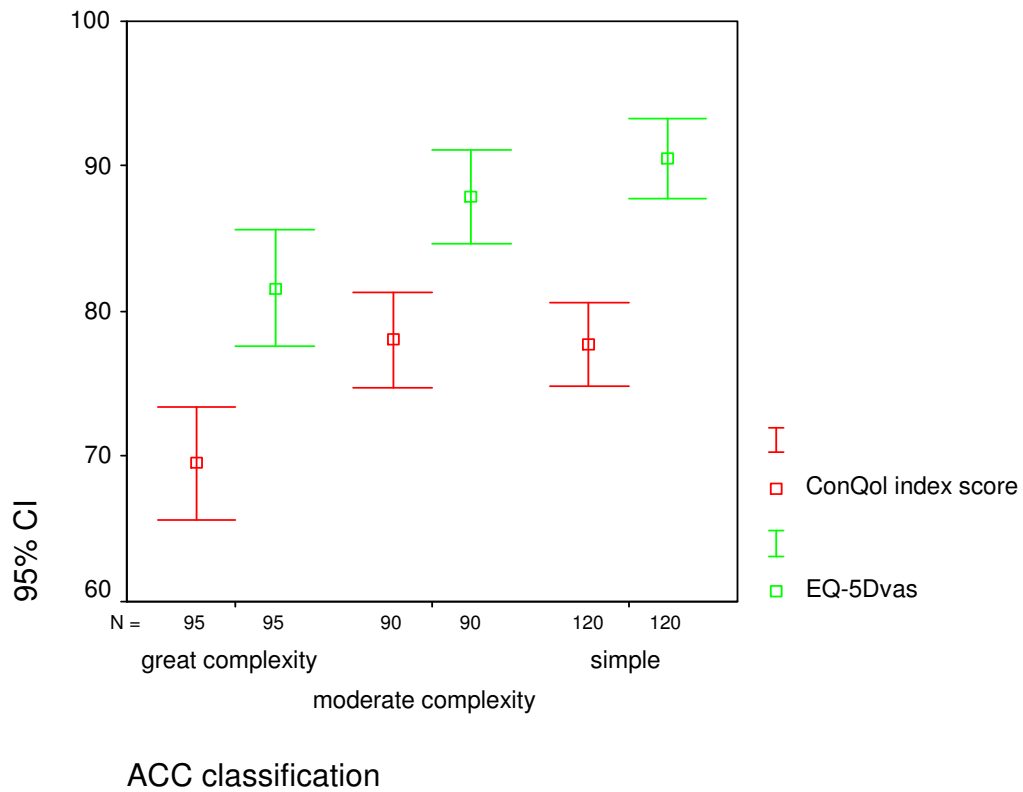
At the other end of the scale, 20% of the sample (N = 65) scored 90 or more. Amongst this group, 25% were classified as having a heart condition of great complexity and 20% reported that their heart condition affected their daily life ‘a little’ or ‘a lot’.

Table 11 and Figure 3 present the mean ConQol index scores by disease severity according to the American College of Cardiology classification, for 8–11 year olds. Children with heart problems classified as being of great complexity had significantly lower ConQol index scores than children with less severe problems. Children who were classified to the simple category had a higher mean ConQol index score than children who were classified as having a heart condition of moderate complexity. However this difference was not statistically significant.

Table 11. Mean ConQol index score by disease severity, according to the American College of Cardiology classification, for 8-11 year olds

	Mean (SD)	95% CI	Median	N
<b>Disease severity</b>				
Great complexity	69.4 (19.2)	65.5–73.3	73.3	96
Moderate complexity	78.2 (15.5)	75.0–81.3	81.2	94
Simple	76.8 (17.2)	73.8–79.9	81.0	124
	P = <0.01			
<b>Heart condition affects daily life</b>				
Not at all	78.9 (16.6)	76.4–81.3	83.3	183
A bit	71.1 (16.3)	68.0–74.2	74.5	107
A lot	57.8 (21.5)	47.7–67.8	59.2	20
	P = <0.001			

Figure 3. Mean ConQol index and EQ-5D vas score by disease severity, according to the American College of Cardiology classification, 8–11 year olds



In terms of self-report of how much their heart condition affected their daily life, there was a decrease in ConQol index scores as children increasingly reported their illness influencing on their day-to-day life (Table 11). The ConQol index score was able to discriminate successfully between all three groups on this measure (Figure 4).

Figure 4. Mean ConQol index and EQ-5D vas score by effect of heart condition on daily life, 8–11 year olds

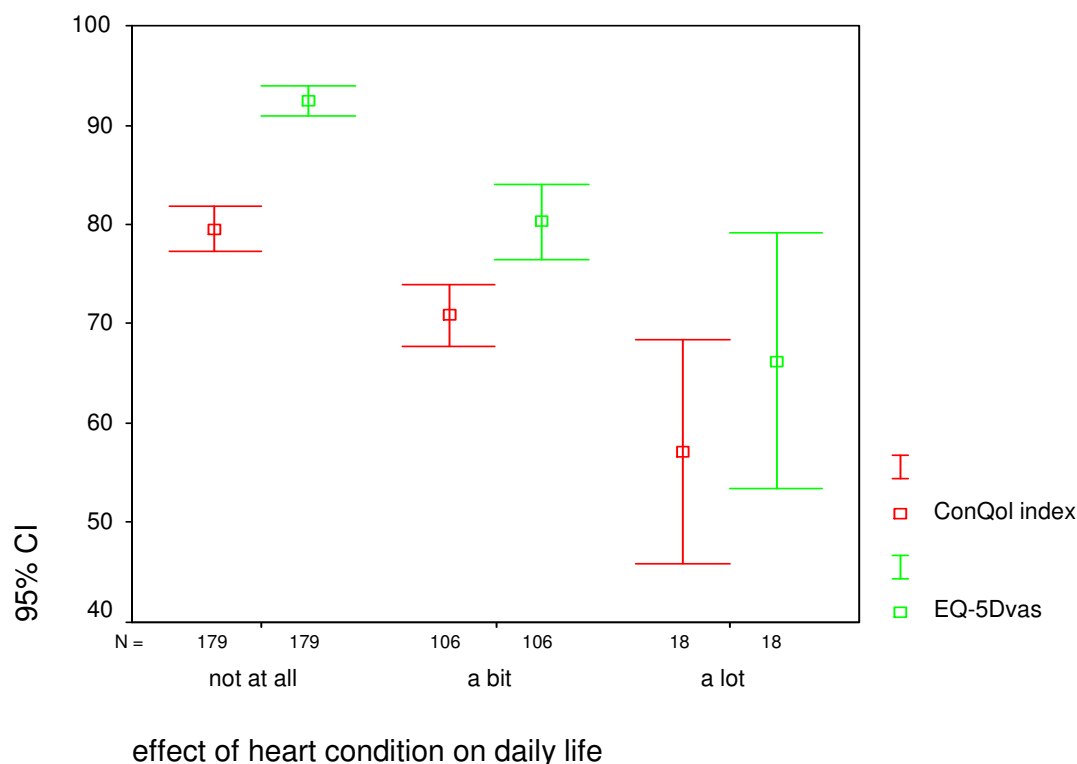


Table 12 shows the proportion reporting any problems on the EQ-5D dimensions by disease severity for this age group. An increasing proportion of problems were reported for all EQ-5D dimensions as disease severity increased. These differences were statistically significant for the mobility, usual activities and pain/discomfort dimensions.

Table 12. Proportion (%) reporting any problems on the EQ-5D dimensions by disease severity, 8–11 year olds

	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/dep
Great complexity	31	11	40	40	35
Moderate complexity	8	3	16	36	28
Simple	7	5	14	25	25
	<0.001	Ns	<0.001	<0.05	ns

Table 13 shows that EQ-5D vas scores decreased (got worse) with increasing disease severity. The mean score for children with conditions categorised as simple was surprisingly high (90.5, SD 14.8). In contrast to the ConQol (where children in the great complexity category had significantly worse scores than those in the other two groups) EQ-5D vas significantly discriminated children in the simple category from those in the moderate and great complexity categories.

Table 13 also shows that children who said that their heart condition did not affect their daily life had significantly higher EQ-5D vas scores than children

who said their heart condition affected their lives a little or a lot. However, unlike the ConQol index score, EQ-5D was did not significantly discriminate between the mean scores for the latter two groups.

Table 13. Mean EQ-5D was score by disease severity and effect of heart condition on daily life, 8–11 year olds

	Mean (SD)	95% CI	N
<b>Disease severity</b>			
Great complexity	81.6 (19.7)	77.6–85.6	95
Moderate complexity	87.9 (15.3)	84.6–91.2	90
Simple	90.5 (14.8)	87.8–93.2	120
	<0.001		
<b>Heart condition affects daily life</b>			
Not at all	92.4 (10.5)	90.9–94.0	179
A bit	80.1 (19.5)	76.5–84.0	106
A lot	66.3 (25.9)	55.4–79.2	18
	<0.001		

Table 14 presents the mean scores on the PesdQL dimensions by disease severity and the effect of heart condition on daily life. For all dimensions (apart from Treatment II) there was a decreasing (worse) score with increasing disease severity.

As with the other two measures, the PesdQL dimensions significantly discriminated between children who were categorised as having a condition of great complexity from the other two groups, where the scores tended to be more similar.

In terms of how much their heart condition affected their daily life, like the ConQol, all the PesdQL dimensions (apart from Treatment II) significantly discriminated between all three groups.

Table 14. Mean scores on the PedsQL dimensions by disease severity and effect of the heart condition on daily life, 8-11 year olds

	Sig	Great	95% CI	Moderate	95% CI	Simple	95% CI
<b>Disease severity</b>							
Physical function	<0.001	69.4 (25.1)	64.3–74.5	80.2 (20.2)	76.3–84.7	86.7 (15.5)	83.8–89.5
Emotional function	<0.001	68.2 (22.9)	63.6–72.9	73.6 (20.2)	69.4–77.8	79.9 (19.2)	76.5–83.4
Social function	<0.001	74.1 (22.4)	69.5–78.6	82.8 (18.3)	79.0–86.6	86.7 (17.1)	83.6–89.8
School function	<0.001	63.8 (22.0)	59.3–68.3	72.2 (20.1)	68.1–76.4	76.0 (17.7)	72.7–79.2
Heart problems + treat	<0.001	60.9 (26.1)	55.5–66.4	73.0 (20.3)	68.8–77.3	79.2 (18.4)	75.8–82.5
Treatment II	Ns	89.4 (13.3)	84.8–94.0	97.6 (4.1)	95.8–99.5	91.2 (15.4)	84.2–98.2
Physical appearance	<0.05	68.8 (30.3)	62.6–75.0	76.7 (24.6)	71.4–82.0	79.5 (23.6)	75.0–84.0
Treatment anxiety	<0.01	68.9 (30.1)	62.7–75.1	81.2 (22.6)	76.4–85.9	80.8 (21.8)	76.8–84.8
Cognitive problems	<0.001	63.9 (22.9)	59.2–68.7	72.6 (24.7)	67.4–77.8	79.1 (21.2)	75.2–83.0
Communication	<0.001	54.7 (28.6)	48.8–60.6	73.3 (23.8)	68.4–78.3	74.1 (24.9)	69.6–78.7
	Sig	Not at all	95% CI	A Bit	95% CI	A lot	95% CI
<b>Heart condition affects daily life</b>							
Physical function	<0.001	89.0 (13.7)	86.0–89.8	68.3 (19.8)	66.1–72.3	44.1 (29.1)	30.4–47.5
Emotional function	<0.0001	82.3 (17.3)	80.5–85.3	64.8 (18.9)	66.6–73.2	50.5 (27.0)	35.6–57.3
Social function	<0.001	89.2 (14.4)	86.4–90.5	73.7 (19.2)	72.1–78.9	52.2 (29.9)	29.5–54.6
School function	<0.001	78.2 (17.0)	75.7–80.5	62.8 (17.9)	59.3–66.6	46.5 (27.1)	30.5–50.7
Heart problems + treat	<0.001	82.1 (15.9)	79.9–84.2	61.3 (19.5)	54.4–62.0	33.7 (27.3)	27.1–39.9
Treatment II	Ns	95.5 (9.8)	90.8–96.9	90.4 (12.9)	91.1–96.3	86.5 (16.5)	72.4–91.4
Physical appearance	<0.001	79.3 (26.2)	74.6–81.4	71.8 (23.8)	64.2–74.7	54.6 (37.0)	24.6–61.7
Treatment anxiety	<0.001	83.9 (21.8)	80.4–87.0	69.9 (26.7)	67.3–77.0	52.8 (27.80)	30.6–64.9
Cognitive problems	<0.001	78.8 (20.7)	72.9–79.3	63.8 (22.7)	59.2–67.6	52.1 (33.3)	30.5–61.3
Communication	<0.001	74.0 (25.1)	72.6–79.3	61.3 (25.5)	54.9–65.2	42.5 (34.7)	27.5–55.8

Of the 12–16-year-old group, 5% (N = 18) had a ConQol index score of less than 50; 33% of these children were classified as having a heart problem of great complexity using the American College of Cardiology classification and 82% said that they felt their heart condition affected their daily life 'a bit' or 'a lot'. In contrast, 16% of the sample (N = 55) scored 90 or more. Amongst this group 30% were classified as having a heart condition of great complexity and 10% reported that their heart condition affected their daily life 'a little' or 'a lot'.

Table 15 and Figure 5 present the mean ConQol index scores by disease severity for 12–16 year olds. Unlike the younger age group, there were no significant differences in ConQol index score by disease severity. However, the ConQol index score was able to discriminate between children in this age group according to how much they reported their heart condition affected their daily life (Figure 6); 10% reported that their heart condition affected their daily life 'a little' or 'a lot'.

Table 15. Mean ConQol index score by disease severity, 12–16 year olds

	Mean (SD)	95% CI	N
<b>Disease severity</b>			
Great complexity	75.0 (17.2)	71.0–79.0	75
Moderate complexity	74.6 (14.2)	72.1–77.0	131
Simple	78.5 (14.5)	75.8–81.2	112
ns			
<b>Heart condition affects daily life</b>			
Not at all	81.6 (11.7)	80.0–83.2	199
A little	69.5 (13.2)	66.9–72.0	106
A lot	53.4 (16.1)	45.7–61.4	18
P = <0.001			

Figure 5. Mean ConQol index and EQ-5D vas score by disease severity, according to the American College of Cardiology classification, 12–16 year olds

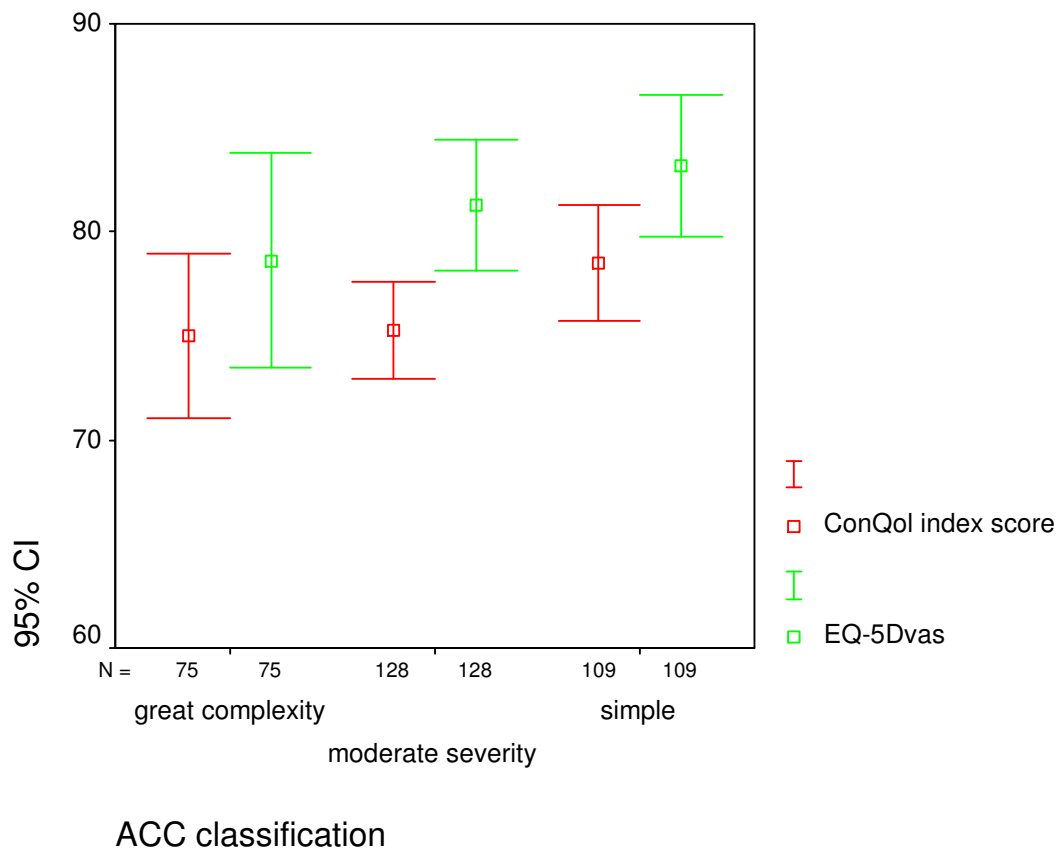
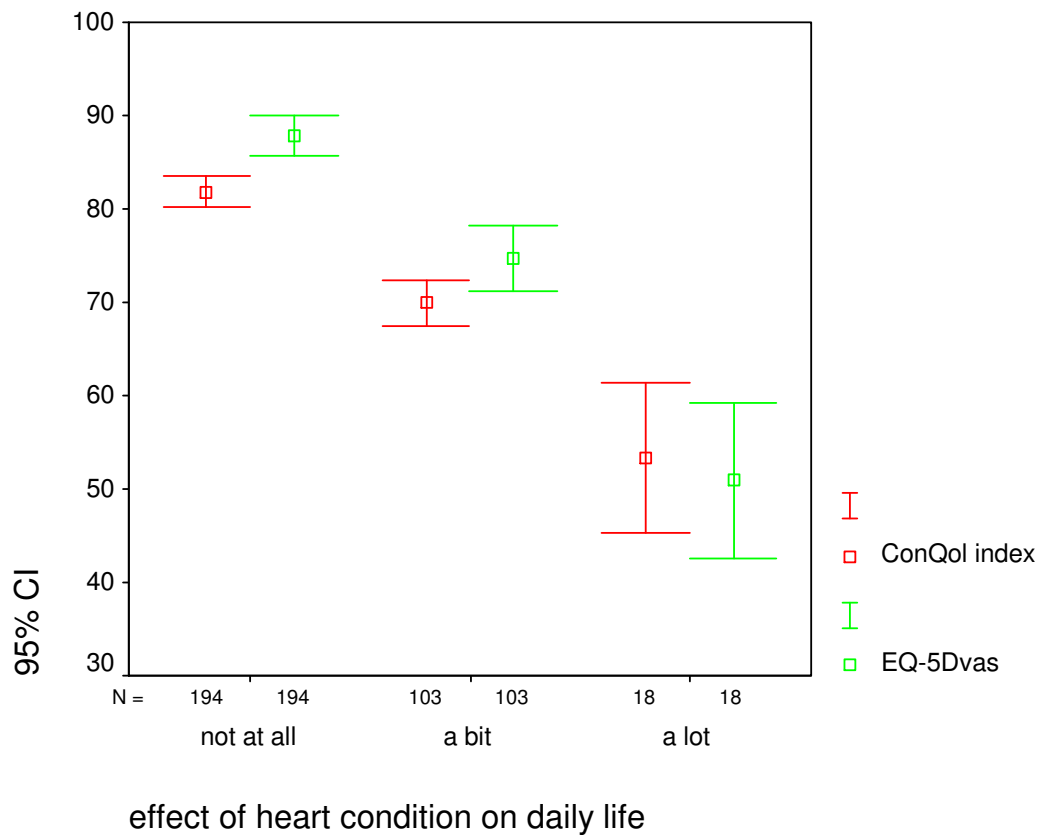


Figure 6. Mean ConQol index and EQ-5D vas score by effect of heart condition on daily life, 12–16 year olds



The proportion of children reporting any problems on each of the EQ-5D dimensions by disease severity showed a similar pattern to that observed for the younger age group. There was an increasing number of problems reported on each dimension as disease severity increased and these differences were statistically significant on the mobility, usual activities and pain/discomfort dimensions (Table 16). There were no significant differences in EQ-5D vas score by disease severity for this age group (Table 17), however like the ConQol index score there were significant differences in EQ-5D vas score according to how much influence children reported their heart condition to have on their daily life.

Table 16. Proportion (%) reporting any problems on each of the EQ-5D dimensions by disease severity, 12–16 year olds

	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/dep
Great complexity	24	4	28	43	24
Moderate complexity	14	3	25	30	30
Simple	6	2	12	25	25
	<0.001	ns	<0.001	<0.05	Ns

Table 17. Mean EQ-5D vas score by disease severity and effect of heart condition on daily life, 12–16 year olds

	EQ-5D vas Mean (SD)	95% CI	N
<b>Disease severity</b>			
Great complexity	78.6 (22.5)	73.4–83.8	75
Moderate complexity	81.3 (17.7)	78.2–84.4	129
Simple	83.2 (17.8)	79.8–86.5	103
	ns		
<b>Heart condition affects daily life</b>			
Not at all	87.8 (15.1)	85.7–89.9	195
A little	74.7 (18.3)	71.1–78.3	103
A lot	50.9 (16.7)	42.6–59.2	18
	<0.001		

Table 18 shows the mean PedsQL scores by disease severity and effect of heart condition on daily life. For this age group there were significant differences in score by disease severity for only two dimensions: physical function and heart problems and treatment. For both of these dimensions, children classified as having a disease in the simple category had significantly lower scores than children with a disease of great complexity. Both the ConQol index and EQ-5D vas also failed to discriminate children in this age group by disease severity. In contrast there were statistically significant differences in PedsQL scores on all the dimensions according to how much children reported that their heart condition affected their daily life.

Table 18. Mean PedsQL scores by disease severity and effect of heart condition on daily life, 12–16 year olds

	Sig	Great complexity	95% CI	Moderate complexity	95% CI	Simple	95% CI
<b>Disease severity</b>							
Physical function	<0.01	72.3 (23.7)	66.8–77.8	78.4 (19.4)	75.0–81.8	83.4 (17.3)	80.1–86.6
Emotional function	ns	77.1 (21.7)	72.1–82.1	76.1 (20.1)	72.9–79.6	77.6 (19.2)	73.9–81.2
Social function	ns	78.4 (21.3)	73.5–83.4	81.6 (21.3)	77.9–85.3	82.9 (18.7)	79.4–86.5
School function	ns	69.2 (22.4)	64.0–74.4	70.1 (20.8)	66.5–73.7	73.1 (20.1)	69.3–77.0
Heart problems + treat	<0.001	63.3 (24.3)	57.6–69.0	71.9 (20.3)	68.4–75.5	76.6 (20.6)	72.7–80.6
Treatment II	ns	87.9 (13.3)	83.2–92.6	94.5 (9.2)	91.6–97.4	94.1 (9.0)	90.2–98.0
Physical appearance	ns	74.6 (25.7)	68.5–80.8	73.1 (29.3)	67.8–78.3	72.2 (25.9)	67.1–77.2
Treatment anxiety	ns	80.6 (24.4)	74.9–86.3	74.4 (27.9)	69.4–79.4	81.4 (24.5)	76.7–86.0
Cognitive problems	ns	69.0 (24.3)	63.4–74.7	70.7 (24.2)	66.4–75.0	71.2 (24.1)	66.6–75.8
Communication	ns	68.8 (24.7)	63.1–74.5	66.3 (28.4)	61.3–71.2	73.2 (26.6)	68.2–78.3
	Sig	Not at all	95% CI	A bit	95% CI	A lot	95% CI
<b>Heart condition affects daily life</b>							
Physical function	<0.001	87.9 (13.6)	86.0–89.8	69.2 (16.1)	66.1–72.3	39.0 (16.6)	30.4–47.5
Emotional function	<0.001	82.9 (17.1)	80.5–85.3	69.9 (16.9)	66.6–73.2	46.5 (21.1)	35.6–57.3
Social function	<0.001	88.5 (14.8)	86.4–90.5	75.4 (16.9)	72.1–78.9	42.0 (24.5)	29.5–54.6
School function	<0.001	78.1 (17.0)	75.7–80.5	62.9 (18.7)	59.3–66.6	40.6 (19.6)	30.5–50.7
Heart problems + treat	<0.001	82.1 (15.1)	79.9–84.2	58.2 (19.3)	54.4–62.0	33.5 (12.0)	27.1–39.9
Treatment II	<0.01	93.9 (9.6)	90.8–96.9	93.7 (8.6)	91.2–96.3	81.9 (15.7)	72.4–91.4
Physical appearance	<0.001	78.0 (23.3)	74.6–81.4	69.4 (26.4)	64.2–74.7	43.1 (36.1)	24.6–61.7
Treatment anxiety	<0.001	83.7 (22.9)	80.4–87.0	72.1 (24.7)	67.3–77.0	47.8 (33.4)	30.6–64.9
Cognitive problems	<0.001	76.1 (22.2)	72.9–79.3	63.4 (21.4)	59.2–67.6	45.9 (30.0)	30.5–61.3
Communication	<0.001	76.0 (23.5)	72.6–79.3	60.1 (26.7)	54.9–65.2	41.7 (27.5)	27.5–55.8

#### 4.11 Summary of the findings in the psychometric testing

##### *Reliability*

The ConQol quality of life scale shows acceptable levels of reliability. The measure shows good internal consistency/homogeneity and the score is stable over a 6-week test-retest period, when respondents have experienced no life events.

##### *Validity*

The performance of the ConQol was comparable to two well-established outcome measures: the condition specific PedsQL and the generic EQ-5D.

## Normative data for the ConQol index score and ConQol symptom score

Table 19. ConQol index by age and sex

		All	Sex		Sig. level of F test
			Males	Females	
All	Mean	75.54	76.41	74.62	0.159
	Count	658	339	319	
	Standard Deviation	16.31	15.19	17.40	
Age 8 to 10	Mean	75.21	75.64	74.67	0.691
	Count	200	110	90	
	Standard Deviation	17.11	16.06	18.40	
Age 11 to 13	Mean	75.01	76.12	73.90	0.277
	Count	278	139	139	
	Standard Deviation	16.99	14.65	19.03	
Age 14 to 16	Mean	76.74	77.80	75.67	0.316
	Count	180	90	90	
	Standard Deviation	14.21	14.98	13.40	
Significance level of F test		0.512	0.583	0.756	

Table 20. Symptom index by age and sex

		All	Sex		Sig. level of F test
			Males	Females	
All	Mean	81.71	82.45	80.93	0.292
	Count	642	330	312	
	Standard Deviation	18.28	17.34	19.22	
Age 8 to 10	Mean	81.89	80.64	83.39	0.294
	Count	195	106	89	
	Standard Deviation	18.15	18.62	17.56	
Age 11 to 13	Mean	81.04	81.91	80.18	0.447
	Count	269	134	135	
	Standard Deviation	18.67	16.72	20.45	
Age 14 to 16	Mean	82.51	85.37	79.58	0.031
	Count	178	90	88	
	Standard Deviation	17.88	16.48	18.85	
Significance level of F test		0.699	0.147	0.353	

Table 21. ConQol index by American College of Cardiology, disease severity

		'ACC' disease severity			Sig. level of F test
		Great complexity	Moderate severity	Simple	
All	Mean	71.87	76.09	77.63	0.002
	Count	171	225	236	
	SD	18.49	14.82	15.95	
Age 8 to 10	Mean	70.39	78.84	76.39	0.018
	Count	66	53	76	
	SD	17.17	13.69	18.50	
Age 11 to 13	Mean	71.07	75.25	77.17	0.086
	Count	62	102	101	
	SD	20.18	16.63	15.30	
Age 14 to 16	Mean	75.30	75.24	80.04	0.119
	Count	43	70	59	
	SD	17.89	12.64	13.28	
Sig. level of F test		0.366	0.305	0.389	

Table 22. Symptom index by American College of Cardiology, disease severity

		'ACC' disease severity			Sig. level of F test
		Great complexity	Moderate severity	Simple	
All	Mean	77.57	82.90	83.77	0.002
	Count	167	218	231	
	SD	20.59	16.71	17.37	
Age 8 to 10	Mean	77.26	82.77	85.59	0.020
	Count	64	51	75	
	SD	18.15	18.32	16.35	
Age 11 to 13	Mean	75.66	82.98	82.35	0.036
	Count	62	96	98	
	SD	22.35	15.89	18.40	
Age 14 to 16	Mean	80.94	82.89	83.82	0.736
	Count	41	71	58	
	SD	21.49	16.83	16.95	
Sig. level of F test		0.441	0.997	0.479	

Table 23. ConQol index by American College of Cardiology, disease severity for males

		'ACC' disease severity			Sig. level of F test
		Great complexity	Moderate severity	Simple	
All	Mean	75.02	77.53	76.53	0.488
	Count	95	120	115	
	SD	17.49	12.40	15.88	
Age 8 to 10	Mean	74.57	78.62	74.22	0.446
	Count	38	34	36	
	SD	16.90	13.28	17.42	
Age 11 to 13	Mean	75.50	76.76	75.80	0.917
	Count	37	48	50	
	SD	16.08	13.29	15.19	
Age 14 to 16	Mean	75.00	77.52	80.67	0.423
	Count	20	38	29	
	SD	21.61	10.54	14.79	
Sig. level of F test		0.974	0.801	0.244	

Table 24. Symptom index by American College of Cardiology, disease severity for males

		'ACC' disease severity			Sig. level of F test
		Great complexity	Moderate severity	Simple	
All	Mean	79.86	84.07	82.92	0.198
	Count	93	117	111	
	SD	18.87	14.71	18.00	
Age 8 to 10	Mean	78.22	83.27	81.83	0.480
	Count	37	32	35	
	SD	18.85	14.71	19.53	
Age 11 to 13	Mean	79.82	83.59	81.03	0.577
	Count	37	46	47	
	SD	16.95	15.18	18.34	
Age 14 to 16	Mean	83.12	85.29	87.29	0.700
	Count	19	39	29	
	SD	22.73	14.43	15.14	
Sig. level of F test		0.659	0.816	0.311	

Table 25. ConQol index by American College of Cardiology, disease severity for females

		'ACC' disease severity			Sig. level of F test
		Great complexity	Moderate severity	Simple	
All	Mean	67.93	74.45	78.68	0.000
	Count	76	105	121	
	SD	19.06	17.09	16.01	
Age 8 to 10	Mean	64.72	79.22	78.34	0.004
	Count	28	19	40	
	SD	16.14	14.75	19.44	
Age 11 to 13	Mean	64.51	73.90	78.50	0.011
	Count	25	54	51	
	SD	23.91	19.14	15.44	
Age 14 to 16	Mean	75.57	72.52	79.44	0.141
	Count	23	32	30	
	SD	14.40	14.47	11.86	
Sig. level of F test		0.069	0.382	0.956	

Table 26. Symptom index by American College of Cardiology, disease severity for females

		'ACC' disease severity			Sig. level of F test
		Great complexity	Moderate severity	Simple	
All	Mean	74.69	81.55	84.56	0.002
	Count	74	101	120	
	SD	22.38	18.75	16.81	
Age 8 to 10	Mean	75.94	81.94	88.88	0.011
	Count	27	19	40	
	SD	17.41	23.64	12.28	
Age 11 to 13	Mean	69.51	82.42	83.56	0.012
	Count	25	50	51	
	SD	27.79	16.64	18.54	
Age 14 to 16	Mean	79.06	79.97	80.35	0.972
	Count	22	32	29	
	SD	20.70	19.19	18.18	
Sig. level of F test		0.327	0.845	0.098	

## Appendix

### ***Calculating ConQol quality of life score by hand***

Reverse score the following items:

- For ConQol 8–11
  - 22 I find it hard to make friends
  - 23 People fuss over me too much
  - 24 I get picked on and teased
  - 25 I feel lonely
  - 28 I think people expect me to do too much
  
- For ConQol 12–16
  - 23 I find it hard to make friends
  - 24 People fuss over me too much
  - 25 I get picked on and teased
  - 26 I feel lonely
  - 28 I think people expect me to do too much
  - 31 I feel like my body is not my own
  - 32 I feel like my health is out of my hands
  - 33 I get fed up with telling people about my health
  - 34 I think about my heart

#### *Calculate a theoretical maximum quality of life score*

Multiply the weight for each quality of life item by 10 (the theoretical maximum response for an item). Sum across all items. The weight for missing items is set to 0, so that they do not contribute to the theoretical maximum score. It is suggested that respondents can be include with up to three missing items.

#### *Calculate a raw quality of life score*

Multiply the response to an item by the weight (Table 1 column 1) for that item. Sum for all items.

#### *Compute the standardised quality of life score*

Divide the raw score by the theoretical maximum score and multiply by 100, which standardises the scores between 0 and 100.

### **Calculating ConQol symptom score**

A symptom score can be calculated if respondents have valid responses using the visual analogue scales for all 13 symptom items. Only one set of weights is available (Table 2)

#### *Calculate a theoretical maximum symptom score*

Multiply the weight for each symptom item by 10 (the theoretical maximum response for an item).  
Sum across all items.

*Calculate a raw symptom score*

Multiply the actual response to each symptom item by the weight (Table 2) for that item. Sum for all items.

*Compute the standardised symptom score*

Divide the raw score by the theoretical maximum score and multiply by 100, which standardises the scores between 0 and 100.

## **Index**

### **Introduction to the measure**

#### **Step 1: qualitative research with children**

- 1.1 The interviews
- 1.2 Results of the interviews

#### **Step 2: Constructing and piloting the measure**

- 2.1 Generating the items from the themes and interviews
- 2.2 Choosing a method for scaling the item responses
- 2.3 Recording the frequency of symptoms
- 2.4 Choosing a recall period
- 2.5 Creating age-appropriate versions
- 2.6 Piloting the initial version of the measure
- 2.7 Changes to the measure resulting from the pilot study
- 2.8 The final version of the measure

#### **Step 3: Determining the weighting and scoring system**

- 3.1 Generating a single index number using weighting
- 3.2 The weighting exercise
- 3.3 Results of the weighting exercise
- 3.4 Weighting of symptom items by clinicians
- 3.5 The scoring method
- 3.6 Managing missing data
- 3.7 Alternative scorings

#### **Step 4: Testing the final version in a national survey to determine validity and reliability and to gather some national norms**

- 4.1 The validation study method and results
- 4.2 ConQol index score: distribution
- 4.3 Missing data
- 4.4 Establishing reliability
- 4.5 Homogeneity
- 4.6 Test-retest reliability
- 4.7 Validity
- 4.8 Relationship between ConQol index score and EQ-5D
- 4.9 Relationship between ConQol index and PedsQL
- 4.10 Validity: discrimination by disease severity
- 4.11 Summary of the findings in the psychometric testing

### **Normative data for the ConQol index score and ConQol symptom score Appendix**

## List of figures

- Figure 1. Distribution of the ConQol index score: 8–11 years  
Figure 2. Distribution of the ConQol index score: 12–16 years  
Figure 3. Mean ConQol index and EQ-5D vas score by disease severity, according to the American College of Cardiology classification, 8–11 year olds  
Figure 4. Mean ConQol index and EQ-5D vas score by effect of heart condition on daily life, 8–11 year olds  
Figure 5. Mean ConQol index and EQ-5D vas score by disease severity, according to the American College of Cardiology classification, 12–16 year olds  
Figure 6. Mean ConQol index and EQ-5D vas score by effect of heart condition on daily life, 12–16 year olds

## List of tables

- Table 1. Weightings from children, parents and clinicians  
Table 2. Weightings from clinicians  
Table 3. Response rate by age  
Table 4. Item-total correlations  
Table 5. Intraclass correlations at six weeks  
Table 6. Percentage reporting EQ-5D dimensions  
Table 7. EQ-5D dimension levels by ConQol index score, 8–11 year olds  
Table 8. EQ-5D dimension levels by ConQol index score, 12–16 year olds  
Table 9. Mean scores on the PedsQL  
Table 10. Correlation (Pearson's  $r$ ) between the PedsQL dimension, ConQol index score and EQ-5D vas  
Table 11. Mean ConQol index score by disease severity, according to the American College of Cardiology classification, for 8–11 year olds  
Table 12. Proportion (%) reporting any problems on the EQ-5D dimensions by disease severity, 8–11 year olds  
Table 13. Mean EQ-5D vas score by disease severity and effect of heart condition on daily life, 8–11 year olds  
Table 14. Mean scores on the PedsQL dimensions by disease severity and effect of the heart condition on daily life, 8–11 year olds  
Table 15. Mean ConQol index score by disease severity, 12–16 year olds  
Table 16. Proportion (%) reporting any problems on each of the EQ-5D dimensions by disease severity, 12–16 year olds  
Table 17. Mean EQ-5D vas score by disease severity and effect of heart condition on daily life, 12–16 year olds  
Table 18. Mean PedsQL scores by disease severity and effect of heart condition on daily life, 12–16 year olds  
Table 19. ConQol index by age and sex  
Table 20. Symptom index by age and sex  
ConQol index by American College of Cardiology, disease severity  
Table 21. Symptom index by American College of Cardiology, disease severity  
Table 22. Symptom index by American College of Cardiology, disease severity

Table 23. ConQol index by American College of Cardiology, disease severity for males

Table 24. Symptom index by American College of Cardiology, disease severity for males

Table 25. ConQol index by American College of Cardiology, disease severity for females

Table 26. Symptom index by American College of Cardiology, disease severity for females

## References

- Hennessey, S. and Kind, P. (2002), 'Measuring health status in children: developing and testing a child-friendly version of EQ-5D', in *19th Plenary Meeting of the EuroQol Group*. York: Centre for Health Economics, University of York.
- Richie, J. and Spencer, J. (1992), 'Qualitative data analysis for applied policy research', in *Analysing Qualitative Data*, A. Bryman and R. Burgess (eds). Routledge: Ondon.
- Uzark, K., Jones, K., Burwinkle, T.M. and Varni, J.W. (2003), 'The Pediatric Quality of Life Inventory<sup>(TM)</sup> in children with heart disease', *Progress in Pediatric Cardiology*, **18**(2): pp. 141–9.
- Warnes, C.A., Liberthson, R., Danielson, G.K., Dore, A., Harris, L., Hoffman, J.E., Sommerville, J., Williams, R.G. and Webb, G. (2001), 'Bethesda Conference Report. Task Force 1: The Changing Profile of Congenital Heart Disease in Adult Life', *Journal of the American College of Cardiologists*. **37**: pp. 1161–98.