

Using the Assessment of Quality of Life (AQoL) Version 1

Please note:

The original AQoL was developed as a 5 dimension, 15 item questionnaire. The first 3 items, about medicine usage, have never been used in the scoring.

At the Centre for Health Economics, only the remaining 12 items (4 dimensions) are used. The instrument is now known as **AQoL 4D Basic**

Previously it was known as AQoL 1. It is also known as AQoL 15 when the original 15 items are included.

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1 The AQoL Instrument

The Australian Quality of Life Project was undertaken to construct and validate a health-related quality of life instrument which would:

1. be a psychometrically appropriate instrument for the evaluation of a range of health interventions, from the medical and pharmacological treatment of acute illness through to health promotion activities; and to
2. enable the economic evaluation of programs through the computation of utilities¹ before and after health-related interventions.

The recent and growing interest in valid and sensitive health-related quality of life (HRQoL) measurement can be traced to three key interacting factors: changes in the predominant types of diseases from infectious to chronic; the introduction of sophisticated medical technology capable of both saving lives and prolonging the lives of the ill; and growing awareness of the limited resources that are available in the health sector (Nordenfelt 1994). The first two factors have increased the importance of HRQoL as an output. The last factor has meant that we must evaluate and discriminate between the increasingly large number of procedures that are available. This implies the need for output measures that are sensitive to HRQoL and that are suitable for use in both summative and economic evaluation.

The *Assessment of Quality of Life* (AQoL) instrument was designed to assist with meeting these two evaluation requirements. The aims were for an instrument which would:

- a) cover the full universe of HRQoL as far as was practicable;
- b) meet standard psychometric requirements for reliable and valid measurement;
- c) be sensitive to a wide range of health states;
- d) be available as a psychometric instrument (yielding 'health state' scores); and
- e) be capable of use as an economic instrument (yielding 'preference' scores); and
- f) be simple to apply.

¹ A distinction is sometimes drawn between 'utilities', derived from the standard gamble technique and 'preferences' derived from the time-trade off (TTO) or other techniques which do not involve measurement 'under risk'. The validity of this distinction has been challenged (eg Winterfeldt and Edwards (1986) and Richardson (1994)). In this paper the term 'utility' is reserved for use with the TTO data, and 'value' is used to describe the non-weighted psychometric data. The AQoL can provide each type of measurement (utility and value). For values, these can be described at the dimension level (thus providing a health status profile based on the five dimensions of the AQoL) or at the AQoL HRQoL level (a single value based on summation of dimension scores). For utilities, the AQoL provides a preference profile based on the four of the five dimensions' utilities (see Figure 10) and an overall AQoL utility score (Figure 11).

In keeping with these aims, the AQoL was developed using standard psychometric procedures as well as being weighted for use in cost utility analysis (CUA). To overcome the limitations associated with valuing composite health states, the AQoL was constructed as a decomposed multi-attribute instrument.

This section provides a brief overview of the construction and validation of the AQoL so that potential users are aware of its underlying properties.

Some issues in psychometric validity

The validity of values obtained from HRQoL-utility instruments depends upon the validity of the descriptive system used and the validity of the numeral values corresponding with each health state that is described. As the accuracy of the numerical values cannot normally be established by direct observation or by comparison with some gold standard, instrument reliability and validity should be determined by establishing a 'nomological net' of evidence assessing the degree of confidence and consequent inferences a researcher can place on the scores obtained by study participants (Cronbach & Meehl 1955; Streiner & Norman 1995).

This net includes instrument content (does it adequately reflect the theoretical universe upon which it is premised?), criteria (how well does the measurement match values obtained from other instruments purporting to measure the same thing?) and construct validity (does the instrument provide scores from which inferences about the defined universe can be made?). Validation of such instruments is an ongoing process and an instrument may prove to be valid in one context but not in another.

Utility weights for economic evaluation

Before the development of cost utility analysis, economic evaluation of health services typically ignored HRQoL or treated it as an 'intangible' that could be noted and described but not quantified or included as an integral part of the health outcome in evaluation research. Cost utility analysis (CUA) attempts to overcome this by adopting the quality adjusted life year (QALY) as the unit of output for health benefits (Torrance 1986).

QALY values have been obtained using one of two broad approaches. With the composite approach, health state scenarios—or complex health state descriptions—have been constructed and numerical values placed upon them using a direct scaling technique. Alternatively, a decomposed approach has been employed using a multi-attribute utility (MAU) instrument. This consists of a generic 'descriptive system' or 'descriptive instrument' and a set of scale values corresponding with each possible health state in the descriptive instrument. As with the scenario-based approach, the values are obtained using one of the standard scaling techniques, *viz.* magnitude estimation, time trade-off, standard gamble, or, most recently, the person trade-off (Murray & Lopez 1996).

The steps used to construct the AQoL involved:

- i) Generating a hypothetical HRQoL model & the various associated dimensions;

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- ii) Developing an item pool to match the dimensions;
 - iii) Administering the item pool to a construction sample;
 - iv) Analyzing the construction sample data to generate an empirical model;
 - v) Comparing the hypothesized & empirical models;
 - vi) Selecting the final model;
 - vii) Scaling it using time-trade off procedures to obtain utility values; and
 - viii) Validating the final instrument.

1.1 AQoL construction

The project commenced with a literature review of the key HRQoL instruments published since the early 1970s. Copies were obtained and subjected to critical analysis. The results suggested twenty aspects of life were important in measuring HRQoL (see Figure 1). A model was subsequently constructed comprising the HRQoL universe, and the five primary dimensions contributing to this universe (illness, independent living, physical ability, psychological wellbeing and social relationships). A pool of items was generated from the literature, interviews and focus groups with 24 clinicians from St Vincent's Hospital (Melbourne) and the Department of Public Health and Community Medicine at The University of Melbourne. Typical items can be found in the AQoL instrument in Appendix I.

Figure 1 **HRQoL dimensions**

Relative to the body	Social expression
– Anxiety/Depression	– Activities of daily living
– Bodily care	– Communication
– Cognitive ability	– Emotional fulfilment
– General health	– Family role
– Memory	– Intimacy/Isolation
– Mobility	– Medical aids use
– Pain	– Medical treatment
– Physical ability/Vitality	– Sexual relationships
– Rest/Fatigue	– Social function
– Sensory functions	– Work function

Following editing and revision of items, the item pool was administered to a construction sample comprising two cohorts: a list sample of 143 patients from St Vincent's Hospital and a random sample of 112 Melbourne residents selected from the telephone directory.

Standard psychometric procedures were used to examine item properties, and items failing to meet specified criteria were discarded. The remaining items were then pooled and a two-stage factor analysis (principal components and varimax) was used to identify redundant items. Reliability analysis was also carried out. These steps were repeated until the most parsimonious solution was derived consistent with psychometric and measurement theory (Anastasi 1976; Rummel 1970; Pedhazur & Schmelkin 1991).

This resulted in an instrument where all items loaded >0.30 on a principal components analysis, suggesting the instrument measures a single underlying construct. In addition five factors were identified, each with three items, as shown in Figure 2. In this figure the columns are the factors and the rows the individual items. For clarity, each resulting scale has been labelled. The average factor item loadings were 0.74 and on cross-factors they were 0.13; these data indicate the five factors were orthogonal to each other, and that each comprised a single scale. That all items loaded on a principal component leads to the conclusion that scores on the five factors can also be combined, thus providing an overall index. The internal consistency of the instrument was appropriate (Cronbach $\alpha = 0.80$).

Figure 2 AQoL factorial structure

Illness	0.86	0.15	0.09	0.07	0.18
	0.86	0.14	0.08	0.07	0.08
	0.84	0.24	0.07	0.06	0.08
Independent living	0.08	0.87	0.07	0.17	-0.02
	0.15	0.71	0.11	-0.03	0.17
	0.27	0.76	0.08	0.14	0.13
Social relationships	0.02	0.06	0.84	0.12	-0.11
	0.10	0.08	0.71	0.08	0.19
	0.16	0.47	0.56	-0.06	0.18
Physical senses	0.14	0.09	-0.05	0.67	-0.15
	0.14	0.08	0.14	0.79	0.13
	-0.13	0.03	0.14	0.68	0.35
Psychological well-being	0.08	0.07	0.11	0.07	0.75
	0.11	0.01	0.46	0.16	0.64
	0.20	0.24	-0.16	0.04	0.53

1.2 AQoL validation

The literature suggests three inter-related forms of validation—content, construct and criterion—are accepted as providing evidence of the nomological net necessary for accepting that a measure possesses validity (Cronbach & Meehl 1955; Pedhazur & Schmelkin 1991; Anastasi 1986).

Content validity refers to the relationship between the hypothesized universe and the measurement: the measurement must provide adequate coverage of the universe. Following the procedures outlined by Lennon (Lennon 1965), the content of each AQoL item was mapped against the HRQoL universe defined through the literature review. The results are given in Figure 3, along with those of several other popular HRQoL utility instruments (the EuroQol/EQ5D (EuroQoL Group, 1990), HUI-III (Torrance et al 1995; Torrance 1996; Feeny, Furlong & Torrance 1996) and 15D (Sintonen 1994; Sintonen 1995) and a standard health profile instrument (the SF-36 (Ware et al 1993)). This comparison shows that the AQoL provides good coverage across the important HRQoL dimensions; coverage which is at least as good, if not better than, comparable instruments.

Figure 3 HRQoL coverage

HRQoL dimensions	SF-36	AQoL	EuroQoL	HUI-III	15D
Relative to the body					
Anxiety/Depression	***	*	*		**
Bodily care	*	*	*	*	
Cognitive ability				*	*
General health	*****				
Memory				*	
Mobility	***	*	*	*	*
Pain	**	*	*	**	*
Physical ability/Vitality	*****			*	*
Rest and fatigue	**	*			*
Sensory functions		**		****	*****
Social expression					
Activities of daily living		*	*		*
Communication		*		**	*
Emotional fulfilment	**			**	
Family role		*			
Intimacy/Isolation		*			
Medical aids use		*			
Medical treatment		**			
Sexual relationships					*
Social function	**	*			
Work function	**				

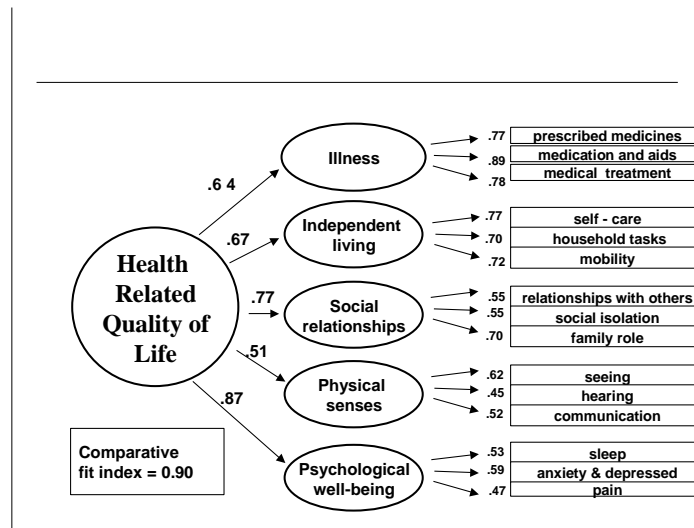
Construct validity refers to how well an instrument's score can be used to infer scores about the underlying psychometric universe or concept that is to be measured. Generally, construct validity is established by examining how well empirical data 'fits' the hypothesized model.

In order to understand the AQoL model it was subjected to structural equation modelling (SEM) (Pedhazur & Schmelkin 1991; McArdle 1996) using a *total disaggregation second order SEM model*, in which each group of items was used to operationalize its respective hypothesized latent dimension. Under these stringent requirements the measures of 'fit'—i.e. estimates of how well a specified model fits the data—typically provide values (around 0.80) below those advocated for less restrictive models, such as total or partial aggregation models (>0.90) (Bagozzi & Heatherton 1994). This model assumed the AQoL dimensions were independent (thus it assumed no correlations between the first level dimension disturbances), and that for each item any common variance was explained by one latent factor only. Analysis of the model, based on correlation and regression weights analysis, confirmed these assumptions (Pedhazur & Schmelkin 1991; McArdle 1996). Under these circumstances the loadings within the model also represent the correlations between the model components.

Figure 4 shows that, on average, the correlations between the five latent dimensions and the manifest items averaged 0.64 explaining an average of 41% of the item variance. The loadings of the five first order latent dimensions on the generic HRQoL index were 0.64 for the Illness scale (explaining 41% of the variance within the Illness scale), 0.67 for the Independent Living scale (45% of scale variance), 0.77 for the Social Relationships scale (59% of scale variance), 0.51 for the Physical Senses scale (26% of scale variance), and 0.87 with the Psychological State scale (76% of

scale variance). The overall comparative fit index (CFI) was 0.90, indicating a much better fit than might be expected under the restrictive conditions of model construction outlined above (Pedhazur & Schmelkin 1991; Bagozzi & Heatherton 1994).

Figure 4 **Structural equation analysis**



Summarizing these results, the analysis indicated that 90% of observed variation between observations may be explained by the structure of the AQoL. There is virtually no addition to explanatory power through relationships not postulated by the model.

Some preliminary evidence is available regarding criterion (concurrent) validity, where the criteria were other independent measures. Three such measures, each measuring an important aspect of HRQoL, are presented here: a measure of functional status (the Barthel Index (Wylie & White 1964; Mahoney & Barthel 1965)) a measure of mood (the Affects Balance Scale (ABS) (Derogatis 1992)), and a measure of general health (the SF-36 (Ware et al 1993)). Since each of these instruments measures a different aspect of HRQoL, moderate correlations — $r = 0.40-0.70$ — between the AQoL and each instrument were expected. Figures 5, 6 & 7 show the regression line and 95% CIs between the AQoL and each of these instruments' scores.

Figure 5 **AQoL/Barthel index**

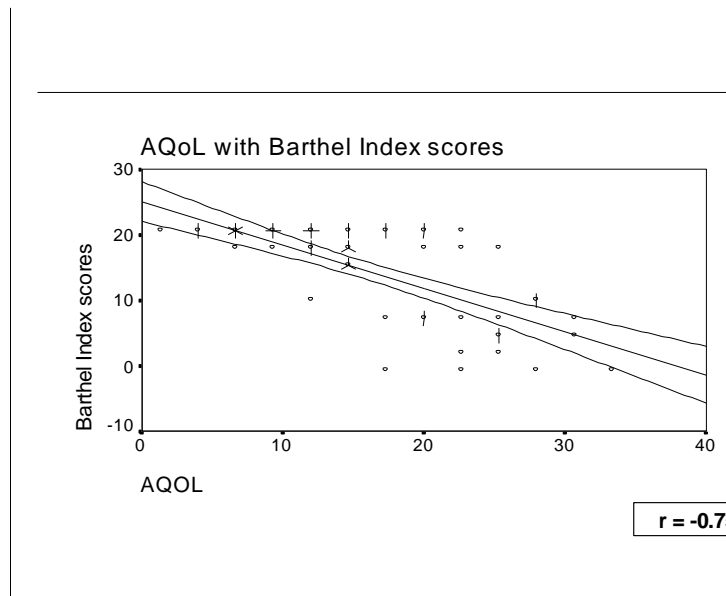


Figure 6 **AQoL/Affect balance scale**

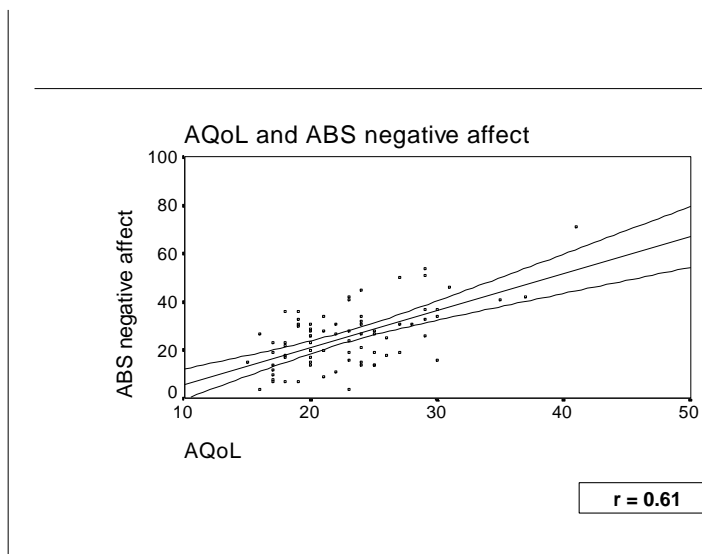
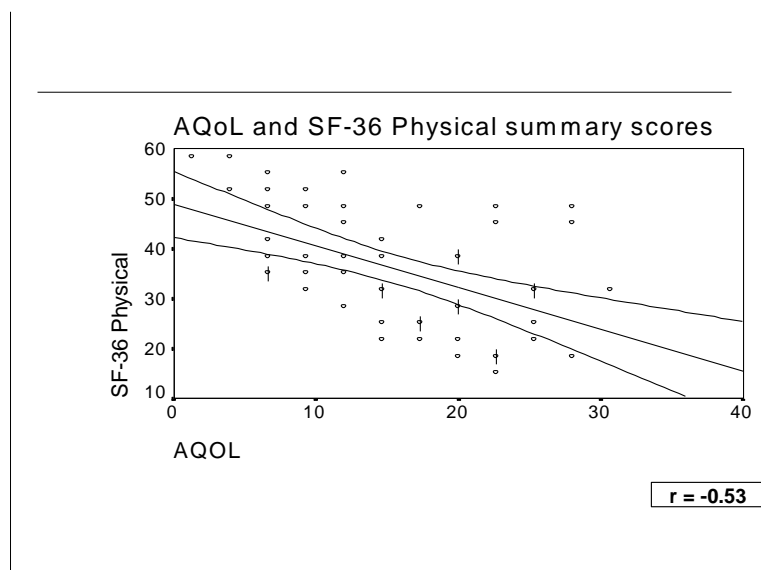


Figure 7 **AQoL/SF-36**



The data in Figure 6 are from 80 people attending a stress management program, and the data in Figures 5 & 9 are from 60 stroke victims assessed by a clinician at three and six months afterwards.

As shown in the three figures, the correlations between AQoL scores and the criterion scores were as expected, given the different instruments were tapping into different aspects of HRQoL. The figures would suggest that the AQoL is sensitive to different affective state levels, that it is sensitive to different levels of functional capability, and it discriminates between those with different levels of general health

1.3 Utilities

The validity of MAU-instruments depends upon the achievement of structural² and preference (utility) independence³. The latter is usually assumed or achieved by careful item selection (Winterfeldt & Edwards 1986; Torrance 1986). The AQoL achieves the former through the orthogonality of its dimensions, as described above (see Figures 2 & 4).

The character of an MAU instrument will reflect three key decisions; viz, (1) which scaling method is used (standard gamble, time tradeoff, etc); (2) what form of model is employed to combine scores (additive, multiplicative or statistical interpolation from the values of a limited number of health states); and (3) the relationship between the initial model scores and utility scores on a life-death scale (direct utility measurement

² Structural independence means that the dimensions are not statistically correlated. This is a required property to prevent the 'double-counting' of some aspect of HRQoL. For example, if the frequency of pain was correlated with disruption to the activities of daily living caused by pain then the inclusion of items measuring both of these attributes could result in the double counting of the disutility of pain.

³ Preference independence is where the value assigned to a response on one item does not depend upon the level of another item. For example, if the disutility of deafness depended upon the quality of personal relationships then there would not be preference independence between these two dimensions Feeny, Furlong & Torrance (1996).

or linkage between the model and a life death scale). For reasons discussed by Richardson (1994) and Dolan et al (1994), scaling was carried out using the time tradeoff technique. Interviews were conducted with a random sample of 350 Victorians within electoral divisions stratified in order of selected characteristics of the Australian population. Respondents were asked to evaluate each item response on an 'item best-worst' response scale; the item worst response was evaluated on a 'dimension best-worst' scale; dimension all worst health states and the instrument all worst health state were measured on a 'good health-death' scale.

The hierarchical model of the AQoL shown in Figure 4 reduced the (inevitable) tradeoff between instrument sensitivity and the need for response orthogonality between dimensions. Within dimensions there was no attempt at achieving structural independence, thereby allowing greater descriptive accuracy. The possibility of double counting was overcome by limiting the possible disutility from each dimension to the disutility of the dimension all worst health state as independently measured.

Since the AQoL represents approximately 1.6 million health states (4^{12} combinations of responses)⁴ direct utility measurement of each state is impossible. Of the two feasible MAU models available—additive and multiplicative—the latter is significantly more flexible and was adopted for modelling each of the five dimensions and the overall instrument score. This model creates a score between 100–0, which must be then recalibrated on a 'good health-death' scale. This was carried out using the single value of the instrument 'all worst health' state on a 'full health-death' scale. If this value is incorrect then all of the MAU values will be systematically biased. When this approach was used with the AQoL a result was obtained which (as elsewhere) predicted lower MAU scores than those directly observed. As a consequence the final utility scores were computed from the four (independent) utility values of the dimensions' 'all worst health' states. While this resulted in significantly higher utility values these have not, to date, been independently validated.⁵

Dis-utility value (DU) results for the 15 items are given in Figure 8, where these were constrained between 0–1. These may be inserted in the first five multiplicative equations presented in Figure 9—the dimension formulae—to estimate an index number for each dimension's utility (on a 100–0 scale, where 100 and 0 represent the index number for the dimension 'all worst' and 'all best' respectively).

⁴ For logical reasons the illness dimension is not used in computing utility scores.

⁵ This situation is not unique: no utility instruments have been reported in the literature as having been independently validated in this way.

Figure 8 Item dis-utility values

Dimension	Item	Health level			
		1	2	3	4
Illness	1.	0.000	0.328	0.534	1.000
	2.	0.000	0.269	0.467	1.000
	3.	0.000	0.166	0.440	1.000
Independent Living	4.	0.000	0.154	0.403	1.000
	5.	0.000	0.244	0.343	1.000
Social Relationships	6.	0.000	0.326	0.415	1.000
	7.	0.000	0.169	0.396	1.000
Physical Senses	8.	0.000	0.095	0.191	1.000
	9.	0.000	0.147	0.297	1.000
Psychological Wellbeing	10.	0.000	0.145	0.288	1.000
	11.	0.000	0.253	0.478	1.000
	12.	0.000	0.219	0.343	1.000
	13.	0.000	0.107	0.109	1.000
	14.	0.000	0.141	0.199	1.000
	15.	0.000	0.104	0.312	1.000

Figure 9 AQoL utility formulae

$$DU1 = (1.1641 * (1 - (1 - 0.3350 * U1) * (1 - 0.5927 * U2) * (1 - 0.4896 * U3)))$$

Equation 1: Illness

$$DU2 = (1.0989 * (1 - (1 - 0.6097 * U4) * (1 - 0.4641 * U5) * (1 - 0.5733 * U6)))$$

Equation 2: Independent Living

$$DU3 = (1.0395 * (1 - (1 - 0.7023 * U7) * (1 - 0.6253 * U8) * (1 - 0.6638 * U9)))$$

Equation 3: Social Relationships

$$DU4 = (1.6556 * (1 - (1 - 0.2476 * U10) * (1 - 0.2054 * U11) * (1 - 0.3382 * U12)))$$

Equation 4: Physical Senses

$$DU5 = (1.2920 * (1 - (1 - 0.1703 * U13) * (1 - 0.2554 * U14) * (1 - 0.6347 * U15)))$$

Equation 5: Psychological Wellbeing

$$U = ((1.04 * ((1 - (0.613 * 0)) * (1 - (0.841 * DU2)) * (1 - (0.855 * DU3)) * (1 - (0.931 * DU4)) * (1 - (0.997 * DU5)))) - 0.04)$$

Equation 6: AQoL utility score

For each dimension there are 64 possible health states, the disutility value of which may be estimated either directly from equations 1–5, (where the values of $U1$ and $U2$ are the item disutility values in Figure 8) or from the disutility values in the look-up tables provided in Appendix II. Note that ‘utility’ scores may be derived from the disutility scores using the formula:

$$U = 1 - DU$$

Formula 1

where D and DU are the dimension utility and disutility values respectively. They represent ‘utility’ scores as they were derived using the TTO procedures. However

the scores are calibrated so that for each dimension the ‘dimension all best and ‘dimension all worst’ utility scores take values of 1.00 and 0.00 respectively. This means that ‘utilities’ from different dimensions cannot be directly compared (as dimension ‘all worst’ health states do not have the same utility values on a life-death scale). For the same reason dimension utilities cannot be compared with utilities measured on a conventional scale where 1.00 and 0.00 represent full health and death respectively.

The disutility values from four of the five dimensions may be combined to produce an overall utility score using Equation 6. The first dimension, Illness, is not used in the computation of utilities. This is because there was a logical problem with respect to it. It had been constructed to reflect an underlying pathological health state. Instead of measuring this directly, we determined to measure it via indicators of health service consumption on the assumption that these would reflect the level of the pathological health state. The difficulty with this approach is that when a person consumes health services (e.g. medication, treatment or use of medical aids) the therapeutic effect of this is lost. Therefore this dimension was omitted from the utility computation. The four dimensions used in utility computation are Independent Living, Social Relationships, Physical Senses and Psychological Wellbeing.⁶

The numbers obtained from the equations refer to utility values on a conventional scale where 1.0 and 0.0 refer to good health and death respectively.

Consistent with the Torrance (1986) HRQoL-health states worse than death can be measured by the AQoL. Torrance argued for an arbitrary lower endpoint of -1.0 .⁷ Although this was used as the theoretical lower boundary when eliciting preferences, the range of utilities for the AQoL ‘all worst health state’ scenario on the ‘full health – death’ scale is -0.04 — $+1.00$. The meaning of the negative scores associated with health states worse than death is as follows. A score of, for example, -0.03 for a particular health state, indicates that a person would regard death as being equally (un)attractive as being in full health for 3% of future years and in health state A (the comparator health state; ‘full health’) for the remaining 97% of future years.⁸ That is, a negative health state implies that a person requires some time in a full health state to compensate them for this option to be equivalent to death.

Regarding the reliability of the AQoL-utility values. The internal consistency for the construction sample’s TTO-values was $\alpha = 0.86$.

⁶ This does not imply that the Illness dimension has no value; it provides an estimate of the value of health care resources consumed. Consequently it is included in the discussion here.

⁷ Preference scores are obtained in a particular context. In the case of the TTO, where positive values are reported this context is the trading-off of years of poor HRQoL from years of ‘full health’. The inferences here are reasonable. By contrast, when TTO values are in the negative range the TTO question requires people to determine that the relationship between ‘full health’ and the health state to be evaluated is such that this relationship is equally desirable as death. This is an unrealistic context and our confidence in the meaning of the preference that is inferred here is correspondingly uncertain: the more extreme negative values cannot be interpreted literally. For a full discussion of this issue, readers should consult Richardson & Hawthorne (2000) Negative Utility Scores and Evaluation of the AQoL All Worst Health State, CHPE, WP73.

⁸ Mathematically this can be expressed as: $0.03U + 0.97 \cdot (1.00) = 0.00$. Solving this gives:

$$U = \frac{-0.03}{0.97} = -0.03.$$

2 Instrument administration

There are several issues which have come to our notice regarding the administration of the AQoL and the coding of AQoL data. This section outlines these issues and discusses how we suggest they should be handled.

In general, the AQoL has proven to be easy to administer, to understand and to complete. The reading level of the AQoL is 71% on the Flesch Reading Ease scale, suggesting its reading level is appropriate for most literate people. Experience with interview administration indicates that it takes about 5-7 minutes to complete. Respondents have also reported it is easy to approach, comprehend and complete.

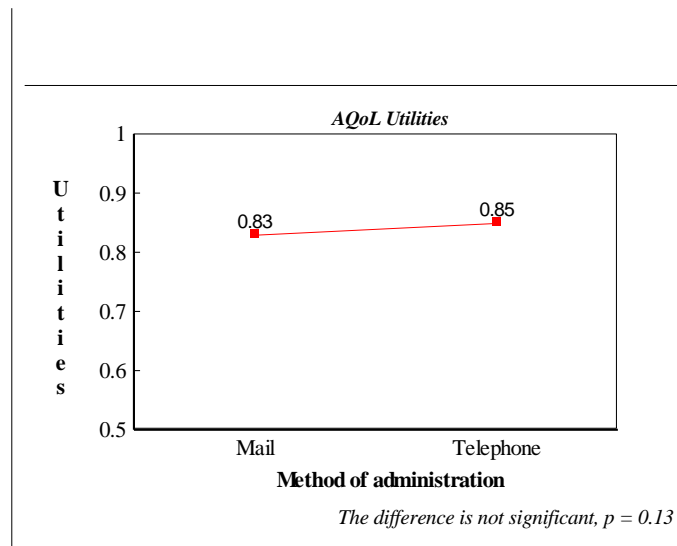
2.1 Mode of administration

The AQoL was designed for self-administration on the assumption that it would primarily be used in field settings where trial participants were able to self-complete: receiving the AQoL either through the mail or being handed it during an interview. This is consistent with Guyatt et al's (1996) findings that self-administration not only increases the response rate but also leads to lower rates of missing data. For this reason, and to personalise the perspective, the items were all written in the first person.

There are, however, situations where the AQoL will be used where other methods of administration will be employed. Typically, these will be either over the telephone, by direct interview or completion by proxy (e.g. by a caregiver).

Most commonly, we expect researchers will be interested in the effect of telephone vs. mail administration. To investigate this, we randomly sampled 139 cases from a health status population survey and asked them to complete the AQoL both by telephone and by mail. Participants were randomly assigned to each method in turn. The interval between administrations was timed to be two weeks: long enough for memory to play little part in the results, yet close enough so that respondents' lives would not have dramatically changed. The results are given in Figure 10 which shows that there was no significant difference in the mean utility score. The Pearson correlation between mail and telephone overall AQoL-utilities was $r = 0.66$. This finding suggest that researchers should not use mixed methods of data collection.

Figure 10 Mail vs. telephone administration



2.2 The time frame

Although no time frame was included within each item, the introductory instructions asked respondents to evaluate their health state over the *previous week*.⁹ Thus items include comments like ‘generally’, or ‘only occasionally’. This was an attempt to overcome the difficulty that respondents’ HRQoL health status—and their assessment of that status—may vary quite considerably within a very short timeframe. Where the timeframe is a long one they may be affected by real health status changes, by the use of drugs, or by recall bias. For example, pain is often episodic. Asking for assessment of their health state *now* or *in the past* may provide misleading assessments.

A key point to note is that this evaluation refers to how the respondent **was** during the past week: it does not ask respondents to assess health state changes within the past week nor to assess the degree of change compared with a previous timeframe. If respondents are confused about this, they should be informed that the AQoL questions ask about their health state during the past week: it is assumed this is a global overall evaluation for that period.

2.3 Items which may cause difficulty

The AQoL has been administered to thousands of respondents with very few reported difficulties. Generally respondents and interviewers have commented that it is easy to understand and to complete. Some of the items, however, may cause some respondents to seek clarification. In general, about 2% of respondents will have a question about the instrument or an item. The items about which questions have been asked are discussed.

⁹ This does not, of course, imply that utility scores only apply to a week. The items in the instrument are used to gain descriptive information about health states. The value of these health states is subsequently inferred from interviews in which the stated duration of the health state is usually much longer. The TTO-values used in the AQoL were obtained using a 10-year timeframe.

Items 1, 2 & 3 Problem of confusing treatment with the outcome. The treatment being evaluated must be excluded from the response. For example, if the treatment consists of a new drug (Drug Q), when respondents in the treatment group are asked to complete Item 1, *Concerning my use of prescribed medicines* and they include Drug Q this may cause them to select a response lower (i.e. to report higher medication use) than they would otherwise select. Respondents should be informed that their responses to these questions should not include the treatment of interest.

Item 2 This item refers to “rely(ing) on medicines or a medical aid”. Two issues have been noted by AQoL users: it is a double-barrelled item probing either reliance upon medicines and/or aids; and it is repetitious of Item 1 which probes the number of prescribed medicines used.

‘Medicine’, as defined during the construction of the AQoL, refers to any remedial substance used to restore or maintain health; a medical aid is similarly defined here as any mechanical or electronic aid used for the same purpose. This would, for example, include a back brace as well as a heart pacemaker; the only aids excluded are glasses or a hearing aid. These were excluded on the grounds that there are explicit questions covering these later in the AQoL; the exclusion avoided double-counting. As such, this item refers to reliance upon the broader family of medicines or medical aids; many of which may not be prescribed by a registered doctor but may be provided by an allied health professional. This may be contrasted with Item 1 which explicitly probes the use of prescribed medicines.

Some respondents also may think that ‘medication’ here refers only to liquid medications; it refers to medications of all kinds, including lotions, liquids and solids.

Item 6 Some respondents have questioned the change in item responses 2 & 3. Response 2 lists getting around the home before getting around the community; response 3 reverses this order.

This change in word order was determined during item trialing when respondents reported that they found it difficult to differentiate between the two levels and tended to respond at random. By reversing the order, it was found that respondents thought more carefully about the issue.

Item 7 This item may cause some respondents some distress for it asks them to reflect upon their intimate personal relationships. We have encountered some people who did not wish to answer this item because it made them feel anxious, worried or depressed.

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- Item 8** See Item 7. The responses to this question are double-barrelled and a person who chooses to be socially isolated or who is socially isolated because of illness may not necessarily be lonely. Where this is the case, the first part of the response should have priority; i.e. a person who is socially isolated but not lonely, would be advised to select option 4 if they asked for clarification.
- Item 13** Some respondents have asked for an intermediate response category between responses 3 & 4 on the grounds that they wake up at night and are usually unable to go back to sleep.
- Logically, these respondents fit response category 4. If they wake up at night and are unable to go back to sleep, then they are awake most of the night. To investigate if this was true, the item was administered in two forms to a sample of 63 cases drawn at random from the generally community and a Melbourne hospital. One form asked the item with the 4-point response scale and the other used a 7-point scale, with interpolated values. Only one case used the interpolated value between responses 3 & 4.
- Item 14** Some respondents have misunderstood the use of the word ‘or’ on the responses, and have assumed they have to suffer from all three afflictions. The responses indicate that a person only needs to suffer from one of these conditions to respond beyond level 1.
- Item 15** Occasionally a person will ask how to gauge how much pain he/she suffers from. He/she should be advised that this is an internal assessment; i.e. his/her own evaluation. We have received one or two enquiries asking whether responses to this should reflect pain status without medication when on medication for pain relief (e.g. use of morphine). The advice should be that this question is to be answered for his/her current situation, irrespective of medication use. Likewise, if a person avoids certain activities because they cause pain, where those activities are avoided the person is not currently in pain.

2.4 Missing data

There are several reasons for missing data occurring in a study. These may be related to the study, or independent of the study. These reasons include: a simple skipping of a page or question (either deliberately or accidentally); a respondent may miss an appointment; they may refuse to complete the AQoL; program staff may forget to administer the AQoL; there may be language or reading difficulties; the respondent may no longer be ill — i.e. they may have recovered, either naturally or because of the treatment —, or they may be too ill (which may be determined by a nurse rather than the patient themselves); they may have died, perhaps naturally or from treatment related causes; some respondents may move home; or they may simply wish to leave the study (e.g. they grow tired of participating).

Grouping these reasons, generally there are two kinds of missing data:

-
- Monotone or censored missing data. This is where a study drop-out is permanent. This may be caused by withdrawal or death. Where a chronic disease is involved, it may be because the patient has been cured or because the treatment doesn't work. It is likely with progressive fatal diseases, such as advanced cancer or AIDS.
 - Intermittent missing data. This is where the missing data is non-permanent. E.g. where a visit is missed, but the subject comes back in the study later. Maybe it is where a question of the AQL is missed, or a whole page.

Generally there are two possible effects of missing data on a study:

1. There will be fewer observations leading to a loss of study power; and/or
2. Where the missing data are non-random, this will lead to bias in study findings. Where subjects are randomized into groups and some drop out of the statistical analysis, this may induce bias which favors one group (Gould 1980).

Consequently it is important that every effort is made to avoid missing data during the collection phase.

Monotone missing data

There is little a researcher can do if faced with substantial monotone AQL missing data. The two traditional ways of handling this situation are to either exclude the withdrawals or to conduct an endpoint analysis. Where the timeframe is reasonable, endpoint analysis is to be preferred.

Exclusion Here the analysis would only include those respondents remaining through to the end of the study. I.e. this allows the researcher to make statements about respondents who remained on the study for part of the full treatment period.

The limitations of this are twofold:

- If the rates of withdrawal between the two groups are different, this will lead to spurious results; and
- If cases withdraw for treatment-related reasons, those remaining in the study may no longer be representative of the population.

Endpoint analysis This is where drop-out cases' last recorded AQL values are used for the final AQL measurement; i.e. respondents' utilities are carried forward. This avoids the problem of non-comparable samples, but gives widely differing data (by time, length of treatment etc). It also assumes that:

-
- The endpoint data would be the 'true' data had the case remained in the study until the end; and
 - There is no distinction in the analysis between true 'observed' data and 'assumed' data.

Intermittent missing data

Based on our experience with the AQoL, an intermittent missing data rate of about 1% per question can be expected in mail surveys.

There are three kinds of intermittent missing data, each of which has different implications for the AQoL findings. They are:

1. Missing completely at random (MCAR). This is where missing data are independent of the AQoL instrument. This includes the respondent moving address,¹⁰ the staff forgot to administer the AQoL (in both these cases the AQoL is missed at, say, baseline, but it may be administered at a follow-up), or an item or page of the AQoL was inadvertently missed. The effect on the study is to diminish the study's power to detect real differences due to the treatment (if they exist).
2. Missing at random (MAR). This is where data are missing independently of the current AQoL data collection, but where they may be explained by previous AQoL or other data collection. This may arise, for example, where there was an unfavorable reaction to previous data collection (e.g. a dislike of the interviewer; or completion of the AQoL causing distress which was not conveyed to the researchers). I.e. MAR involves events which cannot be predicted; their effect on the study findings is uncertain.
3. Not missing at random (NMAR). This is where data are systematically missing for an observable reason. For example, during construction of the AQoL it was noted that 21% of respondents refused to answer questions probing their sexual behaviours; analysis showed these data were missing for particular types of people. Since these were NMAR data which could have biased AQoL scores, these questions were excluded during the construction phase of the AQoL. Examples which may occur in studies using the AQoL could include the death of patients due to their disease, the toxicity of treatment, refusal to answer specific questions etc. Note that these missing data are dependent upon the real current value of the AQoL (e.g. if a person dies their current real utility is '0.0'; if they have been returned to good health it is '1.0'). If there is any reason to assume NMAR, then missing data must be accounted for during data analysis as its omission will bias the study findings (Fairclough 1998).

When handling missing data, it is important to determine which kind of missing data is being reported, and to take whatever steps are appropriate to collect it.

¹⁰ If there is any reason to suspect that the reason for moving is related to the respondent's socio-demographic characteristics, then moving address may not be strictly MCAR.

Often MCAR data can be collected through adequate follow-up reminders (e.g. telephone or interview follow-up to a mail AQoL administration; several follow-ups may be needed). Alternatively, if the MCAR data are a single page or a single item missed, it may be possible to photocopy the AQoL page and forward it to the respondent with a polite note asking him/her to complete it.

For MAR data, it is important to try and identify the cause of the problem. Once this cause has been identified, remedial steps can often be taken to minimize MAR data. For example, inadequate training of an interviewer may cause MAR data. If this can be identified through appropriate audit procedures (e.g. by monitoring interviewer/data relationships), further training can be provided to the interviewer.

If NMAR data are observed, steps should be taken to determine the direction of the bias on the study's findings and this reported along with the analyses. It may be possible to adjust analyses for an identified bias. Consideration should be given to endpoint analysis.

For MCAR and MAR data which remain missing after taking all reasonable collection steps, where this is confined to individual AQoL items, it may be possible to determine the values using one of the following methods. Generally, the most appropriate method will be to model respondents' data. If this cannot be done, the value may be imputed using either of the procedures outlined. The steps taken to handle missing data should always be fully reported.

Modelling values

This involves careful statistical examination of the database in order to model the missing values (usually through use of a regression equation). The procedure is to identify the independent characteristics of all respondents who have responded to the item for which the datum is missing. The characteristics of the missing datum-respondent can then be matched with those who responded. Once a match is found, the average value for the matched cases can be applied.

For example, suppose Respondent A provided these data: Q1: 2; Q2: 2; Q3: X. The characteristics of A (female, >70 years, breast cancer, etc) were matched with those of all other similar cases (female, >70 years, breast cancer, etc). Examination showed that the mean score for Q3: 3. This value would then be assigned to A.

The two advantages of modelling are that the assigned values will not bias the findings nor will they artificially reduce the variance within the database.

The disadvantage of modelling is that it requires a large database and careful analysis. It also requires that the number and type of independent variables collected are carefully thought through prior to any data collection.

Imputing values I: Averaging within cases. This refers to computing each case's average item score within each dimension where there is a missing datum, and then assigning this average score to the missing item. The advantage is that it is simple to do and it reflects the individual's values for the dimension in which the datum is missing.

The disadvantage is that the averaged values may reduce the variance within an AQoL dimension, and thereby bias the true utility value associated with the real condition. This problem becomes even more acute if data are missing from more than one item within a dimension.

For example, consider an individual who responded: Q13: 1; Q14: X; Q15: 3. The averaged response level for Q14 would be $1 + 3 = 4/2 = 2$.

Imputing values II: Averaging across cases. Missing data can be imputed by calculating the average score across all cases and applying this to the item for which the datum is missing. Generally, this method is not recommended and should only be used as a last resort after all else has failed.

For example, for Respondent B, Q9: X. The mean for Q9 across all cases was '1'. This would be assigned to Respondent B, thus Q: 1. The advantage is that this procedure is quick and easy.

The first problem with this procedure is that it imputes a value which may be completely inappropriate (B's responses to the other questions in the dimension might have been Q7: 4; Q8: 4; Q9: X. To impute a value of '1' would probably be highly misleading). The other disadvantage is that it will artificially reduce the variance within an AQoL dimension, and thereby bias the true utility value associated with the real condition. This problem becomes even more acute if data are missing from more than one item within a dimension.

Missing values and the computer algorithm

The computer program in Appendix III contains several lines of computer code which impute values, using the averaging within case approach. These lines will automatically detect when a value is missing from one variable within a dimension and impute the value to be the mean integer value of the two other variables within that dimension. For example, if the data were: Q10: X, Q11: 1, Q12: 3. The program would impute the value for Q10 as $(1+3)/2 = 2$.

Where more than two variables are missing from within any dimension, the research team would have to use one of the techniques above. It is recommended that where

intermittent missing data comprise 30% or more of all responses the case should be discarded.

Note: Missing data are handled by imputing values within each dimension. Regression analysis should not be used to impute values across dimensions because this may violate the statistical independence of each dimension and result in double-counting.

2.5 Using proxies

Although the AQoL was designed for individual self-completion, there will be times when individuals cannot meaningfully complete it. At these times it may be appropriate for others to complete it; this may be preferable to excluding these cases from a study (Sneeuw et al 1997a).

Determining who the proxy should be may be problematic: caseworkers, doctors, spouses, parents or children, and friends may all be available. The most appropriate proxy, however, is the respondent's main caregiver. This caregiver is likely to know their caree's real situation and be able to represent it.

Because there are difficulties with mixing proxy and respondent scores in the one database, the literature on proxy completion of HRQoL-instruments should be consulted. Within this literature there is, generally, considerable variation in the methods used, the selection of appropriate proxies, the procedures recommended and the conclusions drawn. For a review see Sprangers & Aaronson (1992). The substantive conclusions would appear to be that proxies consistently rate the respondent's HRQoL lower than does the respondent him/herself (although this is not the case for all dimensions of HRQoL) (Sneeuw et al 1997b); and clinicians seem particularly prone to misrating pain and social relationship levels. We have found that proxies' scores are consistently lower than respondents, and that this is particularly evident on the Social Relationship dimension (Hawthorne, Herrman & Thomas 2000).

There is also general agreement that a proxy's ratings are influenced by his/her own health state, particularly where there is an onerous caregiver burden. Other factors affecting a caregiver's responses include a false consciousness of the true state of affairs, differences in perception and valuing, and that there may be mutual dependence (Raphael 1996).

Where proxies are used, it is strongly recommended that a stratified analysis be undertaken in order to determine the impact of the proxies' scores on the study findings. Where such an analysis demonstrates that proxies' scores make a major contribution to the study findings, it is recommended that adjusted proxies' scores are computed and used in the data analysis.

2.6 Sample size

One of the most commonly asked questions relates to the sample size required by researchers to demonstrate differences as a result of an intervention. Since the AQoL is a new instrument, many of its properties are not yet known, including its sensitivity under different circumstances and with different populations.

Consequently no definitive sample size estimates can be given; the sample size needed for any particular study should be worked out by the researchers who have expertise in their particular field. It is recommended that this process involves a statistician with whom the researchers can directly liaise.

Subject to this caveat the following advice may be found useful.

Issues in sample size calculation

Sample size calculation is concerned with including sufficient subjects in a study to avoid Type I and Type II errors.¹¹ Sample size calculations only ever specify the minimum number of subjects for a study: confounding requiring stratification during analysis is invariably ignored and requires greater numbers of subjects. Also, as the n increases, the standard deviation also approaches the true population standard deviation. Several things follow from this:

- As the sample size increases the variance will diminish (i.e. the sd or $95\%CI$ will become narrower, hence the argument to 'increase the sample size' to obtain a significant result). However, since a distribution resembles a normal distribution beyond about 30 cases, if a pilot study has >30 cases it can be assumed that increasing the sample size will not make huge differences to the sd or $95\%CI$ for calculating the main study sample size.
- Where a study involves several criteria, sample sizes should be calculated for each criteria. If the criteria are of equal importance, the largest calculated sample should become that used in the study. If one criterion is the 'gold standard', the sample size for this should be used.
- It also follows that with a large enough sample size the null hypothesis will always be rejected.

The issue for sample size calculation is to have a large enough sample to demonstrate a true effect if there is one, but small enough to avoid rejecting the null hypothesis when it should be accepted. When calculating sample size there are five key issues:

- The 'size' of a test (α);
- The 'power' of a test ($1-\beta$);
- The 'effect' of the variable of interest (δ);
- The 'variability' of the variable (sd); and
- The 'unit of analysis'.

¹¹ However, it should be noted that sample size calculation does not demarcate between studies worth pursuing and those not worthy.

The size of a test (α)

This is the probability of the researcher making a Type I error (α ; i.e. concluding there is a difference when there really is no difference). The probability of a Type I error should be set by the researcher at the research design stage. The conventional level is $p = 0.05$, i.e. there is a 5% chance of committing a Type I error.

The power of a test ($1-\beta$)

The power of a study is the probability of the researcher making a Type II error ($1-\beta$; i.e. concluding that there is no significant program effect when there really is a program effect). The lower the power the less certain a researcher can be of the results. The power of a test depends on the size of the effect a researcher wishes to detect and the consequent determined sample size needed to detect this effect. High power requires valid, reliable and sensitive instruments especially where a large sample is not possible. In either case, however, the calculation of power is a necessary prerequisite for the calculation of the required sample size. In medical research the convention is for power to be set at 0.80. In evaluation and educational research — where the effect size is usually small (see below) — the power of a study is often set at 0.90.

The effect of the variable of interest

When a new program or treatment is introduced it will be expected to have a greater effect than the program or treatment with which it is being compared. The unit of measurement used is delta (δ or d). This can be thought of as the effect size of the treatment (also referred to as the *critical effect size* [Δ] when the question is asked: how small does the increase in a score have to be to be of importance? Thus Δ describes the *determined effect size* while δ refers to the *obtained effect size* (Kraemer & Thiemann 1987). δ is one standard deviation from the mean of an obtained score, i.e. one z-score unit. In general the effect size for non-paired data can be calculated by the formula:

$$\delta = \frac{\bar{X}_e - \bar{X}_{ne}}{sd_{ne}}$$

Formula 2

Where:

\bar{X}_e = the mean score of the experimental group,

\bar{X}_{ne} = the mean of the comparator group, and

sd_{ne} = the standard deviation of the control group. In a pre-post test the sd is the pooled standard deviation (ie sd_{pooled}) (Cohen 1988).

In the medical field the accepted interpretation of δ is that:

- 0.00 – 0.29 = a small effect

-
- 0.30 – 0.49 = a moderate effect
 - 0.50 – 0.69 = a good effect
 - 0.70+ = a large effect (Cohen 1988).

The accepted effect size for a study should take into consideration the practical real-world values of findings. Extremely small effect sizes, although statistically significant, may not justify the effort of finding them, or, if they are found, have a great deal of practical value. It is prudent, therefore, to adopt realistic effect size values.

The variability of the variable (sd)

Where two groups are to be compared, this is simply the standard deviation of the control group. For paired data (e.g. pre-treatment and post-treatment AqoL scores) the pooled standard deviation can be used. It can be estimated from:

- A pilot study
- Previously published studies
- An informed estimate (e.g. if the AqoL mean score was expected to be 0.75, then the informed estimate for the *sd* might be 0.08 based on a guess of 10%).

The unit of analysis

Where programs are administered to groups of people (e.g. respondents from two hospitals, or from three communities), it has been argued that the unit of analysis should be the group rather than the individual.¹² Statistical tests, such as independent t-tests and analysis of variance are based on the assumption that the units of data used for the analysis are independent. Subjects in groups may not necessarily be independent of each other; they may interrelate in some way such that they form clusters (e.g. where a treatment is administered to the group or where people come from separate clinics or hospitals). The effect of clustering is to reinforce common knowledge, attitudes and behaviors. Under these conditions the statistical assumption of independence of the error term is violated leading to a Type I error (i.e. concluding there is a program effect when there is actually no effect). Consequently it has been argued that group means should be used in order to avoid violating the independence assumption underlying many statistical tests (McCullagh & Nelder 1983). This clustering effect can be controlled for by increasing the sample sizes above the minimum required. Where it is likely clustering occurs, researchers should consult with a statistician and the relevant literature on intra-cluster correlation for computing sample sizes.

Sample sizes for the AqoL

¹² This does not apply to paired data, where individuals may act as their own controls through providing pre- and post-treatment scores. It does apply, however, whenever there is a control group with which the treatment group's scores are being compared.

Sample size estimates under a variety of assumptions are presented in Figure 11. These estimates are based on the following parameters, which are those most commonly experienced by researchers. It is assumed the study design comprises cases randomized into treatment and comparator groups of equal size, and that post-treatment AQoL scores are to be compared (i.e. use of an independent or dependent t-test or Mann-Whitney U-test, depending on the data distribution).

- The 'size' of the test (α) has been set at $p = 0.05$.
- The 'power' of the test ($1-\beta$) has been set at 0.80.
- The 'effect' (δ) of the variable of interest is presented for a range of estimates; from 0.10 through to 1.00.
- The 'unit of analysis' is assumed to be the individual case.

If the assumption is made that $sd_e = sd_{ne}$ (which usually implies that the two samples are similar sized¹³), then the generic sample size formula for estimating the n in each group can be used:

$$n = \frac{2sd^2 \cdot (Z_\alpha + Z_{1-\beta})^2}{(\mu_e - \mu_{ne})^2}$$

Formula 3

This can be simplified (Formula 10) where the effect size is predetermined, as in Figure 11:

$$n = \frac{2 \cdot (Z_\alpha + Z_{1-\beta})^2}{\delta^2}$$

Formula 4

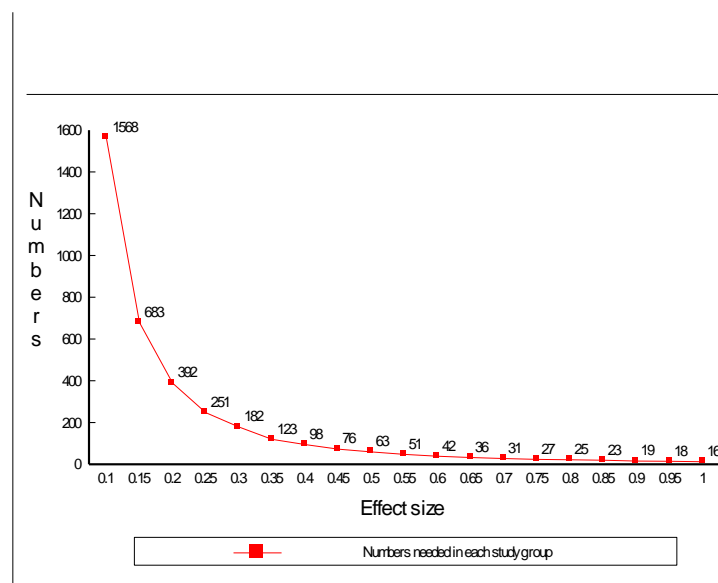
- sd is estimated as described above.
- Z_α is for a two-sided test, with $p = 0.05$, $z = 1.96$
- $Z_{1-\beta}$ is for set for 80% power, thus $1-\beta = 0.20$, $z = 0.84$
- $\mu_e - \mu_{ne}$ in Formula 3 is the specified difference between population means. This should be determined by the smallest estimated clinically significant difference

¹³ This is usually true; there may, however, be situations where the numbers in each group are equal but the variance within the groups different.

- δ is the predetermined effect size of interest. This should be determined by the smallest estimated clinically significant difference which is important; i.e. for sample size calculation it should be assumed that $\Delta = \delta$.

When using Figure 11 to estimate minimum sample sizes, once an estimate of δ has been made, the corresponding number of subjects required for each cohort in the study can be read off on the Y-axis. For example, if in a study of a new drug for blood pressure, the Δ was estimated to be 0.25 and it was assumed that $\Delta = \delta$, the numbers in each group of the study would need to be 251, i.e. 502 subjects would need to be recruited into the study and then randomly assigned to treatment/comparator groups.

Figure 11 Sample size



2.7 Languages other than English

The AQoL has not been translated into any languages other than English.

Where a non-English-speaking person is to be administered the AQoL, it is recommended a professional interpreter is employed. The quality of the translation both from English and back into English cannot be assumed where an untrained interpreter (e.g. family member) is used given the difficulties of achieving accurate concept and language equivalence (Orley & Kuyken 1994).

2.8 Changing AQoL items

There may be times when researchers wish to alter AQoL items.

The AQoL was designed to be used as a generic instrument applicable across a wide variety of healthcare interventions where the utility values would enable comparisons of interventions and/or economic evaluation. As such it is important that the results from different studies can be directly compared. The validity of such comparisons is determined by the use of a common instrument. We recognise, however, that all interested AQoL users reserve their own rights to publish information to further the

validity and reliability of the AQoL; any investigator who wishes to publish such a finding is asked to submit a copy of their manuscript to the AQoL development team for review. Where such a review indicates that the AQoL scoring algorithm has been modified, researchers should not refer to their scores as 'AQoL utility' scores.

So that researchers can use the AQoL confident that their results are truly comparable with those obtained elsewhere, the AQoL has been copyrighted and may not be used or modified without the written consent of the authors.

This restriction is not intended to discourage use of the AQoL, rather it is in the interests of all researchers as it ensures a standard instrument is available. It enables researchers to use the AQoL in full confidence that AQoL support is available, and that their results will be directly comparable with those obtained by others.

Where a more detailed assessment of particular health-states associated with a disease is required, the AQoL should be used in conjunction with a disease-specific instrument. Bowling (1991 & 1995) provides an introduction to many disease-specific instruments.

3 Scoring the AQoL

Given the psychometric and utility properties outlined in Section 1, the AQoL can be scored in two ways, depending upon the purpose of the researcher.

3.1 Data entry and initial coding

Data coding in general

When entering data from the AQoL into a computer database, the data entry will be found easiest if the rank order of item responses are entered, thus:

- 'A' = '1'
- 'B' = '2'
- 'C' = '3'
- 'D' = '4'

I.e. the higher the numerical score, the poorer the respondent's HRQoL.

This coding scheme also has the advantage that these values can be directly used to compute either summated ratings or utilities as described in the next sections.

The data should be double-entered with range-checking, and the database cleansed. Original variables should be retained and transformed/dummy variables used in all subsequent analyses.¹⁴

¹⁴ This protects the database should coding errors be made at any stage of the analyses. Ideally, a copy of the database should be used for all analyses so that the original database is kept intact.

Handling special cases

In some cases, respondents will have decided that the response options to an item are inappropriate and do not describe their situation accurately. They may either select two options, or make a written comment next to the question. Coding these cases can be difficult. Whilst different approaches can be taken to these problems, we recommend the following procedures.

- ◆ Where a person selects two responses to the one item:
 - If the two options are consecutive, the respondent should be given the benefit of the doubt and the response denoting the better health state used. E.g. if to Q11 a respondent selected 'B' and 'C', this would be coded as 'B'.
 - If the two options are non-consecutive, the mean value should be assigned. E.g. if to Q11 the respondent had selected 'A' and 'C', then a value of 'B' should be assigned.
- ◆ Where a respondent has made a written comment:
 - If they have selected a response choice this choice should be respected and used.
 - If no item response has been selected, the comment should be used as a guide for assigning a value. E.g. if to Q11 no response has been selected, but the respondent has written "I find it difficult to hear in a crowd where other people are talking", this could be assigned a 'B' on the grounds that the respondent is indicating they have "some difficulty hearing".

3.2 As an unweighted, psychometric instrument providing 'value' profiles

Where a researcher wishes to provide a HRQoL-profile, the responses to individual items can be summed. This method will provide value profiles of illness, independent living, social relationships, physical senses and psychological wellbeing. These can then be summed to provide an overall unweighted HRQoL-index.

This method of scoring the AQoL is simple and straightforward: no weighting of items is required. The disadvantage is that no claims can be made regarding utilities or preferences (i.e. the resulting scores cannot be used in economic evaluation). It should also be noted that when used in this way, the AQoL does not provide profiles of health status: the profiles are of HRQoL.

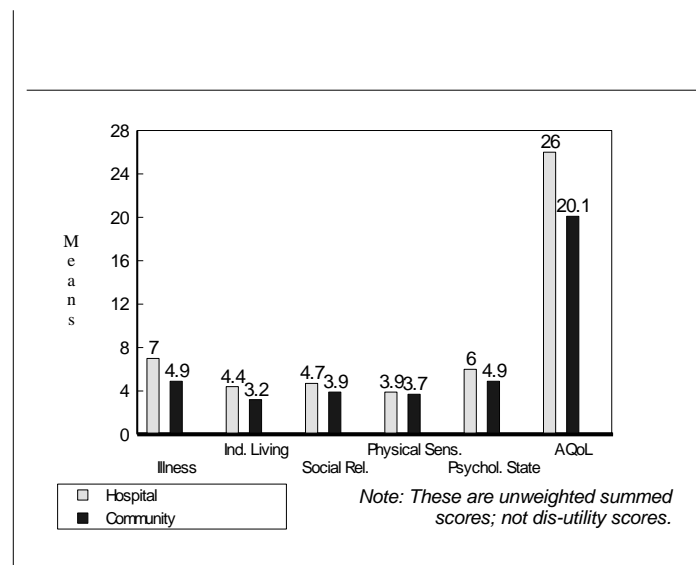
For data analyses, item responses should be recoded as follows:

- '1' = '0'; i.e. if the first response is selected, the respondent's status is 'good' and there is no loss of HRQoL.
- '2' = '1', '3' = '2' and '4' = '3'.

This coding will produce scores for each scale ranging from '0–9', where '0' represents 'good' HRQoL and '9' the worst possible HRQoL for the dimension of interest. This transformation does not alter the differences between responses, but ensures that a person with good health obtains a score '0'; if this transformation is not undertaken a person in good health will obtain a score of '3' on each scale or '15' on the summed AQoL.

After transformation, when summed into a single HRQoL-score, AQoL scores will range from '0–45', where '0' represents 'good' HRQoL and '45' the worst possible AQoL HRQoL-score.

Figure 12 Typical AQoL scores by hospital status



At the time of writing, no population norms have been established. Evidence from several studies, however, suggests that the pattern of scores presented in Figure 12 can be expected. This shows the average obtained scores from two studies involving comparison of hospital and general community cases (n = 318). These are indicative only and should not be taken as norms.

3.3 As a utility HRQoL measure

Where utility values are required, the raw AQoL data as described in Section 3.1 is used (*not* the recoded values). These raw scores will need to be transformed using the values and formulae presented in Figures 8 & 9. Since this is a cumbersome and tedious task to perform by hand, manual calculation of AQoL-utilities is not recommended. Not only is it time-consuming, but it can also lead to errors. To alleviate this problem, we have developed both 'look-up' tables for the dimensions and a data analysis program for SPSS.

In addition, the AQoL utilities can be used to calculate QALYs for use in economic evaluation.

3.3.1 Calculating utilities

Using look-up tables

The look-up tables in Appendix II (Table 1 to Table 5) provide disutility values for each of the five AQoL dimensions. Although the tables avoid using Equations 1-5, the obtained dimension utilities still have to be manually entered into Equation 6 for utility computation. This manual method may be suitable for very small data sets, although we recommend against it.

To use the look-up tables, Figures 13 & 14 should be consulted. Figure 13 provides a descriptive worked example based on the dimension shown in Figure 14, Independent Living. Figure 14 shows how to read a look-up table.

Figure 13 Look-up table: worked example

A person needs help with the more difficult personal care tasks, they need no help with household tasks, and they cannot get around the community by themselves.

- The AQoL scores:
Q4: 3 Q5: 1 Q6: 3
- The health state is described as:
3,1,3
- From Figure 15 or Table 2, the value for this health state is:
 $DU_2 = 0.4672$
- Contribution of this to his/her AQoL utility using Equation 6:
$$U_{AQoL} = 1.04(1 - 0.613^3)(1 - 0.84^1(0.4672))$$

$$(1 - 0.855^3 DU_1)(1 - 0.93^1 DU_2)(1 - 0.997^3 DU_3) - 0.04$$

Figure 14 Using look-up tables: independent living

Items & health state levels				
	1	2	3	Disutilities ¹
3	1	1		0.2700
3	1	2		0.4249
3	1	3		0.4672
3	2	1		0.3639
3	2	2		0.5012
3	2	3		0.5388
3	2	4		0.7853
3	3	1		0.4020
3	3	2		0.5322

The headings here refer to AQoL item numbers

The entries here are the AQoL item response levels selected by respondents

The values here describe the disutility for a person in the health state described by their item responses

Data analysis by computer

This is the most efficient method of data analysis, and can be readily adapted for almost any situation. The necessary computer algorithms are provided in Appendix III. Although they have been presented in a format suitable for use by SPSS (SPSS 1996) there is no particular reason SPSS has to be used. The program has been written in a format that will work with all versions of SPSS and with any suitable SPSS data file, following the modifications described below. Although this means the program is longer and simpler in construction than strictly necessary it enables all researchers to use it easily and to modify it for use with other data analysis programs, including those in the public domain, such as EpilInfo (Dean et al 1994).

Before modifying the program, it should be typed in exactly as is, saved and run in SPSS¹⁵. If the results are identical with those provided below, the program has been correctly typed in and may be modified as described. Until these results are obtained, the program will need to be checked for errors; most likely typing errors.

Description of the program

- Lines 33–38 Define the dummy data to be used to test the program. This assumes the AQoL item variables are named Q1, Q2, Q3 etc. If other variable labels are used, these should be modified accordingly. This also assumes the data are in fixed field format. The data columns specified for each variable relate to the sample data set in Lines 41–62. If the data are in columns other than those provided here, the column numbers will need to be modified.
- Line 39 Defines missing data as being coded '9'. If missing data have been coded as some other character, this line will need to be modified.
- Lines 41–62 These are sample dummy data. Once the program has been successfully run and the results below obtained, these lines may be either omitted or replaced with 'live' data.
- Lines 64–102 Impute missing values.
- Lines 104–118 Set up transformed AQoL variables. This procedure keeps the original data intact, thereby enabling the original data to be used for other analyses (e.g. computing simple summated AQoL HRQoL-scores).
- Lines 120–179 Recodes the AQoL variable responses to their respective utility weights. These lines should not be modified: any modification will cause invalid computation of utilities.
- Lines 181–185 Compute the disutilities for each AQoL dimension. Again, these lines should not be modified under any circumstances.

¹⁵ It can be directly downloaded from the CHPE website <http://ariel.unimelb.edu.au/chpe/>

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- Lines 187–191 Compute the utilities for each AQoL dimension.

 - Lines 195–200 Compute the AQoL utility score. These lines should not be modified under any circumstances.

 - Lines 202–204 Simply print out the AQoL dimension disutility utility scores and the AQoL utility scores for each case. These lines have been included to enable checking of the program with the small database in Lines 41–62. Once the program has been successfully run these two lines can be omitted.

Obtained results

Once the program has been typed in and saved (preferably as an *.sps file, but any extension can be used) it should be run using the provided dataset to check for errors. Although this dataset does not check all program lines, it enables a researcher to proceed with some confidence. The values were assigned as a test pattern and as such they have no particular meaning.

The obtained results should be identical to those shown in Figure 15. Note:

- Case #1 has no loss of utility. This is the highest value available for the AQoL. Any scores higher than 1.0 indicate an error in the data or the program.

- Cases #16–20 are reporting that death would be preferable to their HRQoL situation. Case #20 is the worst utility measured by the AQoL. Any scores below –0.04 will indicate an error in the data or program.

- The obtained DU...n values should be identical with those provided in the five lookup tables in Appendix II. This can always be used as an internal check when running the program.

Figure 15 Sample AQoL utility data analysis

ID	DU1	DU2	DU3	DU4	DU5	AQOL
001	.00	.00	.00	.00	.00	1.00
002	.21	.00	.00	.00	.00	1.00
003	.21	.00	.00	.12	.00	.88
004	.00	.10	.10	.12	.00	.73
005	.21	.00	.12	.06	.05	.80
006	.29	.21	.00	.18	.11	.60
007	.29	.21	.00	.30	.11	.52
008	.36	.10	.26	.06	.13	.57
009	.29	.36	.21	.14	.31	.32
010	.29	.38	.18	.37	.15	.29
011	.21	.38	.36	.31	.33	.20
012	.36	.31	.12	.39	.15	.34
013	.36	.21	.44	.32	.02	.33
014	.00	.74	.20	.27	.34	.12
015	.62	.29	.75	.23	.31	.11
016	.35	.36	1.00	.55	.31	.00
017	.75	.95	.82	.48	.02	-.01
018	.88	.92	.79	.56	.11	-.01
019	.77	.29	.51	.74	.92	-.03
020	1.00	1.00	1.00	1.00	1.00	-.04

3.3.2 Using the AQoL to estimate QALYs

The term Quality-adjusted life years (QALYs) refers to utility values existing over time; the formula is simply:

$$QALY = U * t$$

where U is the utility value of a health state and t is the length of time in years spent in that health state. If a person obtained an AQoL utility of 0.75 and they were in that health state for 5 years, the QALY-value would be $0.75 * 5 = 3.75$.

In order to use utilities to produce QALYs, three conditions must be met: (a) the utility weights must be based on preferences, (b) these preferences must be anchored on a 0.00–1.00 scale where 0.00=death and 1.00=good health (note that this allows health states worse than death) and (c) the preferences must form an interval scale, have a ‘strong interval’ property (Richardson 1994). Due to its design and construction procedures the AQoL meets (a) and (b). Demonstrating that the AQoL meets requirement (c) is difficult and has yet to be proven. In this, however, the AQoL is not alone: no test of this ‘strong interval’ property has been devised and no utility instruments have been proven to meet this requirement; it is assumed that existing instruments have it because of the scaling procedures used during preference elicitation and the combination rules followed to produce the utilities.

QALYs are usually used as an outcome measure in evaluations. The gain in QALYs due to the treatment would be the difference in QALYs between the intervention group and a suitable comparator group. Where costs are collected, the cost-per-QALY can be calculated enabling direct comparison with other interventions which have cost-per-QALY values known. Normally the intervention with the lowest cost-per-QALY gain would be preferred on the grounds of gaining a better health outcome for the least monetary input. For a more detailed discussion of QALYs and their uses readers should consult Drummond et al (1998) Methods for the Economic Evaluation of Health Care Programmes.

4 AQoL: Questions and Answers

We are committed to making it easy for everyone to use the AQoL through supporting researchers in their efforts to evaluate health programs. There are a number of questions which researchers commonly ask. In this section we present the most common questions we have been asked and provide answers. The questions cover two broad areas:

- Issues around economic evaluation and the use of generic utility instruments, of which the AQoL is an example; and
- Questions clarifying the uses and limitations of the AQoL instrument.

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Appendix 1 The AQoL instrument

The AQoL instrument: Version A¹⁶

(For interview or mail self-administration.)

¹⁶ Copyright © Centre for Health Program Evaluation. All rights reserved. This material incorporating the AQoL instrument cannot be reproduced or applied without the prior written consent of the authors. This copyright is in the interests of all researchers as it ensures a standard instrument is available. This enables researchers to use the AQoL in full confidence they will be supported, and that their results will be directly comparable with those obtained by others.

INSTRUCTIONS: ***This questionnaire has 12 questions and will take less than ten minutes. The questions are about your health during the last week. Please circle the alternative that best describes you during the last week.***

- 1 Do I need any help looking after myself?
- A. I need no help at all.
 - B. Occasionally I need some help with personal care tasks.
 - C. I need help with the more difficult personal care tasks.
 - D. I need daily help with most or all personal care tasks.
- 2 When doing household tasks: *(For example, preparing food, gardening, using the video recorder, radio, telephone or washing the car)*
- A. I need no help at all.
 - B. Occasionally I need some help with household tasks.
 - C. I need help with the more difficult household tasks.
 - D. I need daily help with most or all household tasks.
- 3 Thinking about how easily I can get around my home and community:
- A. I get around my home and community by myself without any difficulty.
 - B. I find it difficult to get around my home and community by myself.
 - C. I cannot get around the community by myself, but I can get around my home with some difficulty.
 - D. I cannot get around either the community or my home by myself.
- 4 Because of my health, my relationships *(For example: with my friends, partner or parents)* generally:
- A. Are very close and warm.
 - B. Are sometimes close and warm.
 - C. Are seldom close and warm.
 - D. I have no close and warm relationships.
- 5 Thinking about my relationship with other people:
- A. I have plenty of friends, and am never lonely.
 - B. Although I have friends, I am occasionally lonely.
 - C. I have some friends, but am often lonely for company.
 - D. I am socially isolated and feel lonely.
- 6 Thinking about my health and my relationship with my family:
- A. My role in the family is unaffected by my health.
 - B. There are some parts of my family role I cannot carry out.
 - C. There are many parts of my family role I cannot carry out.
 - D. I cannot carry out any part of my family role.

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- 10 Thinking about my vision, including when using my glasses or contact lenses if needed:
- A. I see normally.
 - B. I have some difficulty focusing on things, or I do not see them sharply.
For example: small print, a newspaper, or seeing objects in the distance.
 - C. I have a lot of difficulty seeing things. My vision is blurred.
For example: I can see just enough to get by with.
 - D. I only see general shapes, or am blind. *For example: I need a guide to move around.*
- 8 Thinking about my hearing, including using my hearing aid if needed:
- A. I hear normally.
 - B. I have some difficulty hearing or I do not hear clearly.
For example: I ask people to speak up, or turn up the TV or radio volume.
 - C. I have difficulty hearing things clearly. *For example: Often I do not understand what said. I usually do not take part in conversations because I cannot hear what is said.*
 - D. I hear very little indeed. *For example: I cannot fully understand loud voices speaking directly to me.*
- 9 When I communicate with others: *(For example: by talking, listening, writing or signing)*
- A. I have no trouble speaking to them or understanding what they are saying.
 - B. I have some difficulty being understood by people who do not know me. I have no trouble understanding what others are saying to me.
 - C. I am only understood by people who know me well. I have great trouble understanding what others are saying to me.
 - D. I cannot adequately communicate with others.
- 10 If I think about how I sleep:
- A. I am able to sleep without difficulty most of the time.
 - B. My sleep is interrupted some of the time, but I am usually able to go back to sleep without difficulty.
 - C. My sleep is interrupted most nights, but I am usually able to go back to sleep without difficulty.
 - D. I sleep in short bursts only. I am awake most of the night.
- 11 Thinking about how I generally feel:
- A. I do not feel anxious, worried or depressed.
 - B. I am slightly anxious, worried or depressed.
 - C. I feel moderately anxious, worried or depressed.
 - D. I am extremely anxious, worried or depressed.

12 How much pain or discomfort do I experience?

- A. None at all.
- B. I have moderate pain.
- C. I suffer from severe pain.
- D. I suffer unbearable pain.

Appendix II AQL dimension disutility look-up tables

Table 1: Illness items, health state levels and disabilities

<i>Items & health state levels</i>				<i>Items & health state levels</i>			
<i>1</i>	<i>2</i>	<i>3</i>	<i>Disutilities</i> ¹	<i>1</i>	<i>2</i>	<i>3</i>	<i>Disutilities</i> ¹
1	1	1	0.0000	3	1	1	0.2083
1	1	2	0.0946	3	1	2	0.2860
1	1	3	0.2508	3	1	3	0.4142
1	1	4	0.5700	3	1	4	0.6763
1	2	1	0.1856	3	2	1	0.3607
1	2	2	0.2651	3	2	2	0.4260
1	2	3	0.3964	3	2	3	0.5338
1	2	4	0.6647	3	2	4	0.7541
1	3	1	0.3222	3	3	1	0.4728
1	3	2	0.3907	3	3	2	0.5290
1	3	3	0.5036	3	3	3	0.6218
1	3	4	0.7345	3	3	4	0.8113
1	4	1	0.6900	3	4	1	0.7748
1	4	2	0.7285	3	4	2	0.8065
1	4	3	0.7921	3	4	3	0.8587
1	4	4	0.9222	3	4	4	0.9654
2	1	1	0.1279	4	1	1	0.3900
2	1	2	0.2121	4	1	2	0.4529
2	1	3	0.3512	4	1	3	0.5568
2	1	4	0.6353	4	1	4	0.7690
2	2	1	0.2931	4	2	1	0.5134
2	2	2	0.3639	4	2	2	0.5663
2	2	3	0.4808	4	2	3	0.6536
2	2	4	0.7196	4	2	4	0.8320
2	3	1	0.4147	4	3	1	0.6043
2	3	2	0.4757	4	3	2	0.6498
2	3	3	0.5762	4	3	3	0.7249
2	3	4	0.7817	4	3	4	0.8784
2	4	1	0.7421	4	4	1	0.8488
2	4	2	0.7764	4	4	2	0.8745
2	4	3	0.8330	4	4	3	0.9168
2	4	4	0.9487	4	4	4	1.0032

1 = Based on means

Table 2: Independent living items, health state levels and disabilities

<i>Items & health state levels</i>				<i>Items & health state levels</i>			
<i>4</i>	<i>5</i>	<i>6</i>	<i>Disutilities</i> ¹	<i>4</i>	<i>5</i>	<i>6</i>	<i>Disutilities</i> ¹
1	1	1	0.0000	3	1	1	0.2700
1	1	2	0.2054	3	1	2	0.4249
1	1	3	0.2615	3	1	3	0.4672
1	1	4	0.6300	3	1	4	0.7452
1	2	1	0.1244	3	2	1	0.3639
1	2	2	0.3066	3	2	2	0.5012
1	2	3	0.3563	3	2	3	0.5388
1	2	4	0.6831	3	2	4	0.7853
1	3	1	0.1749	3	3	1	0.4020
1	3	2	0.3476	3	3	2	0.5322
1	3	3	0.3948	3	3	3	0.5678
1	3	4	0.7046	3	3	4	0.8015
1	4	1	0.5100	3	4	1	0.6547
1	4	2	0.6201	3	4	2	0.7377
1	4	3	0.6501	3	4	3	0.7604
1	4	4	0.8476	3	4	4	0.9094
2	1	1	0.1032	4	1	1	0.6700
2	1	2	0.2893	4	1	2	0.7502
2	1	3	0.3401	4	1	3	0.7720
2	1	4	0.6740	4	1	4	0.9159
2	2	1	0.2159	4	2	1	0.7186
2	2	2	0.3810	4	2	2	0.7897
2	2	3	0.4260	4	2	3	0.8091
2	2	4	0.7221	4	2	4	0.9366
2	3	1	0.2617	4	3	1	0.7383
2	3	2	0.4182	4	3	2	0.8057
2	3	3	0.4609	4	3	3	0.8241
2	3	4	0.7417	4	3	4	0.9450
2	4	1	0.5653	4	4	1	0.8691
2	4	2	0.6650	4	4	2	0.9120
2	4	3	0.6922	4	4	3	0.9237
2	4	4	0.8712	4	4	4	1.0008

¹ = Based on means

Table 3: Social relationships items, health state levels and disabilities

<i>Items & health state levels</i>				<i>Items & health state levels</i>			
<i>7</i>	<i>8</i>	<i>9</i>	<i>Disutilities</i> ¹	<i>7</i>	<i>8</i>	<i>9</i>	<i>Disutilities</i> ¹
1	1	1	0.0000	3	1	1	0.2891
1	1	2	0.1014	3	1	2	0.3623
1	1	3	0.2049	3	1	3	0.4370
1	1	4	0.6900	3	1	4	0.7872
1	2	1	0.0617	3	2	1	0.3337
1	2	2	0.1572	3	2	2	0.4025
1	2	3	0.2545	3	2	3	0.4728
1	2	4	0.7108	3	2	4	0.8022
1	3	1	0.1241	3	3	1	0.3787
1	3	2	0.2135	3	3	2	0.4423
1	3	3	0.3046	3	3	3	0.5090
1	3	4	0.7317	3	3	4	0.8173
1	4	1	0.6500	3	4	1	0.7583
1	4	2	0.6880	3	4	2	0.7858
1	4	3	0.7268	3	4	3	0.8138
1	4	4	0.9085	3	4	4	0.9450
2	1	1	0.1234	4	1	1	0.7300
2	1	2	0.2128	4	1	2	0.7602
2	1	3	0.3040	4	1	3	0.7910
2	1	4	0.7315	4	1	4	0.9354
2	2	1	0.1778	4	2	1	0.7484
2	2	2	0.2619	4	2	2	0.7768
2	2	3	0.3477	4	2	3	0.8058
2	2	4	0.7498	4	2	4	0.9416
2	3	1	0.2328	4	3	1	0.7670
2	3	2	0.3115	4	3	2	0.7936
2	3	3	0.3918	4	3	3	0.8207
2	3	4	0.7683	4	3	4	0.9479
2	4	1	0.6962	4	4	1	0.9235
2	4	2	0.7297	4	4	2	0.9348
2	4	3	0.7639	4	4	3	0.9464
2	4	4	0.9241	4	4	4	1.0005

1 = Based on means

Table 4: Physical senses items, health state levels and disabilities

<i>Items & health state levels</i>				<i>Items & health state levels</i>			
<i>10</i>	<i>11</i>	<i>12</i>	<i>Disutilities</i> ¹	<i>10</i>	<i>11</i>	<i>12</i>	<i>Disutilities</i> ¹
1	1	1	0.0000	3	1	1	0.1181
1	1	2	0.1226	3	1	2	0.2320
1	1	3	0.1921	3	1	3	0.2965
1	1	4	0.5600	3	1	4	0.6381
1	2	1	0.0860	3	2	1	0.1980
1	2	2	0.2023	3	2	2	0.3059
1	2	3	0.2681	3	2	3	0.3671
1	2	4	0.6169	3	2	4	0.6910
1	3	1	0.1625	3	3	1	0.2690
1	3	2	0.2731	3	3	2	0.3717
1	3	3	0.3357	3	3	3	0.4299
1	3	4	0.6675	3	3	4	0.7380
1	4	1	0.3400	3	4	1	0.4388
1	4	2	0.4375	3	4	2	0.5243
1	4	3	0.4926	3	4	3	0.5756
1	4	4	0.7850	3	4	4	0.8471
2	1	1	0.0595	4	1	1	0.4100
2	1	2	0.1777	4	1	2	0.5023
2	1	3	0.2446	4	1	3	0.5545
2	1	4	0.5993	4	1	4	0.8313
2	2	1	0.1424	4	2	1	0.4747
2	2	2	0.2545	4	2	2	0.5622
2	2	3	0.3179	4	2	3	0.6117
2	2	4	0.6542	4	2	4	0.8741
2	3	1	0.2161	4	3	1	0.5323
2	3	2	0.3228	4	3	2	0.6155
2	3	3	0.3831	4	3	3	0.6626
2	3	4	0.7031	4	3	4	0.9122
2	4	1	0.3872	4	4	1	0.6658
2	4	2	0.4812	4	4	2	0.7391
2	4	3	0.5344	4	4	3	0.7806
2	4	4	0.8163	4	4	4	1.0006

¹ = Based on means

Table 5: Psychological wellbeing items, health state levels and disabilities

<i>Items & health state levels</i>				<i>Items & health state levels</i>			
<i>13</i>	<i>14</i>	<i>15</i>	<i>Disutilities</i> ¹	<i>13</i>	<i>14</i>	<i>15</i>	<i>Disutilities</i> ¹
1	1	1	0.0000	3	1	1	0.0240
1	1	2	0.0853	3	1	2	0.1077
1	1	3	0.2558	3	1	3	0.2751
1	1	4	0.8200	3	1	4	0.8288
1	2	1	0.0465	3	2	1	0.0696
1	2	2	0.1287	3	2	2	0.1503
1	2	3	0.2932	3	2	3	0.3117
1	2	4	0.8370	3	2	4	0.8454
1	3	1	0.0657	3	3	1	0.0884
1	3	2	0.1466	3	3	2	0.1679
1	3	3	0.3085	3	3	3	0.3268
1	3	4	0.8440	3	3	4	0.8523
1	4	1	0.3300	3	4	1	0.3479
1	4	2	0.3935	3	4	2	0.4102
1	4	3	0.5205	3	4	3	0.5348
1	4	4	0.9406	3	4	4	0.9471
2	1	1	0.0235	4	1	1	0.2200
2	1	2	0.1073	4	1	2	0.2908
2	1	3	0.2747	4	1	3	0.4323
2	1	4	0.8286	4	1	4	0.9004
2	2	1	0.0692	4	2	1	0.2586
2	2	2	0.1499	4	2	2	0.3268
2	2	3	0.3114	4	2	3	0.4632
2	2	4	0.8453	4	2	4	0.9145
2	3	1	0.0880	4	3	1	0.2745
2	3	2	0.1675	4	3	2	0.3416
2	3	3	0.3264	4	3	3	0.4760
2	3	4	0.8522	4	3	4	0.9203
2	4	1	0.3475	4	4	1	0.4938
2	4	2	0.4099	4	4	2	0.5465
2	4	3	0.5345	4	4	3	0.6519
2	4	4	0.9470	4	4	4	1.0004

¹ = Based on means