

Report from the Joint WGEA/QOLC Task Force on Utilities Assessment

For the NCIC-CTG
September 2001
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1.0 Issue

The NCIC-CTG is recognized as a world leader in incorporating health related quality of life (HRQOL) measures into cancer clinical trials. The Quality of Life Committee (QOLC) is the standing committee that coordinates this activity. More recently, the NCIC-CTG has been developing expertise and policies for incorporating economic evaluations into cancer clinical trials. The Working Group on Economic Analysis (WGEA) is the working group that is spearheading this activity. The QOLC and WGEA recognize that the question of whether the NCIC-CTG should be incorporating utility assessments into their cancer clinical trials is an important issue that relates to both of their mandates. Accordingly, a task force comprised of members from both the WGEA and QOLC was established to prepare a report and bring forward recommendations on utility assessment as part of NCIC-CTG clinical trials.

1.1 Background

Economic analysis requires that we be able to measure what the costs and benefits of an intervention are before we can consider whether the intervention is “worth its cost”. Although collecting data on costs has its own complexities, we can usually collectively agree on what costs to collect, how they will be gathered, and what interpretation we will place on them. In the cost arena, costs are measured in dollars which serves as a common denominator of resource use and allows us to add together quantities of disparate resources to achieve an agreed upon measure of overall cost for a patient and for a trial.

The measurement of benefits is complicated by the absence of a measure that can aggregate disparate benefits, such as overall survival, progression free survival, and pain into a single measure of benefit. Patients may value particular benefits differently and there is no obvious way to add together benefits for an individual or for a trial to yield a measure of overall benefit that can be compared with overall costs. What we need is a common denominator for benefits that can play the same role as dollars (or money generally) do as the common denominator for costs.

Beginning in the 1970's health economists started exploring the measurement of overall benefit by asking patients what they thought about various health states, such as “living with lung cancer” or the “impact of severe arthritis”. Although patients might possibly make an overall assessment of their situation, there remained no way to “add together” the experience of different patients.

Early economic analysis of clinical trials and less controlled interventions tended to select a single dimension of benefit as the primary end point, most often survival. This could be acceptable if benefits were predominantly survival; different survival experiences of patients could then be added together to get a measure of overall benefit that could be compared with measures of overall costs. However, this approach is not acceptable where there are multiple dimensions of benefits to take into account. Furthermore, these benefits could not be added together for a single patient, let alone added together for all patients in a trial.

“Utilities” arose to address the need for a common denominator to measure benefits. Two concepts “Time Trade-off” and “Standard Gamble” were developed to determine how a patient compared two health states in terms of their feeling about remaining in a current health state or (conceptually) moving to a preferred health state with less survival. These “feelings” have been termed, “preferences”, “valuations” or “utilities”. The patient's feeling about a health state takes

account of the various aspects of the health problem and how the patient values each aspect, and serves as a common denominator for that patient and his/her situation. For the most part we have added together responses of patients to get an overall measure of benefits. The methodology of determining utilities is not finally settled and developments in this area are ongoing.

Generally speaking, "utilities" represent how a person values a particular health state that is "imperfect" (in contrast to "perfect health"). That is, utilities refer to the formal and explicit measurement of a respondent's evaluation of relevant outcomes in a medical context. The concept of utility is derived from economic decision theory, and in medicine, as in economics, utilities are meant to describe the values that people assign to outcomes.

Some authors distinguish between "utility measurement", and "valuation". In this nomenclature, a utility represents a judgment of the value of an uncertain outcome (one that can be represented as having a probabilistic occurrence). A valuation, in contrast, refers to a judgment of the worth of a health state when that outcome is known to occur. Many authors do not make this distinction and use the term "utility" in both instances, as we do here.

1.2 Relationship between Utilities and Health Related Quality of Life (HRQOL)

For the purpose of this discussion, patient-based health status questionnaires such as the EORTC QLQ-C30 will be referred to as "traditional" HRQOL instruments. Direct and indirect measures (see section 3.3) of health state preferences will be referred to as "utilities". Assessment of utilities provides different but complementary information to traditional HRQOL assessment.

As described above (section 1.1), utilities are a measure of preference for a given health state anchored between death and optimal health. They acknowledge risk and uncertainty of outcomes in choices patients face and in clinical decision making. As a measure of benefits, utilities can be used as a weighting factor to adjust survival by quality of life. The length of time in a given health state can be multiplied by the utility weighting factor to derive quality adjusted life years (QALYs). This also allows calculation of cost-utility ratios.

The information derived from traditional HRQOL assessments and utility assessments can be utilized to describe different but complementary attributes of a patient population and comparison of patient groups with the same disease. However, depending on whether a disease-specific or generic traditional HRQOL instrument was used, only utility assessments may be able to compare patient groups with different diseases (i.e., the "common denominator" described in section 1.1). As well, only utilities provide a single meaningful measure that can be incorporated in health policy and cost-utility analyses.

2.0 Process

A meeting was held in Ottawa on June 12, 2001. Attending the meeting were E. Grunfeld, D. Coyle, H. Walker, HJ Au and K. Somers. Dr. M. Brundage was unable to attend the meeting. The elements of the report and recommendations were agreed at that meeting. The report was then drafted by E. Grunfeld and circulated to the members of the Task Force for review and comment. A joint meeting of the WGEA and QOLC was held in October 2001. The draft report was discussed, recommendations for revisions, made and the report was revised accordingly. The revised report was distributed to the broader membership of the WGEA and QOLC for further comment.

3.0 Summary of Issues

3.1 Should the NCIC-CTG incorporate utility assessment into selected trials?

It was considered important for the NCIC-CTG to begin to incorporate utility assessments into selected trials for the following reasons:

1. Cancer is an appropriate disease to which to apply these methods: there may be small differences in survival (or surrogate measures of survival such as disease-free interval, response rate, etc), making measures of morbidity, such as HRQOL, more important. Decisions must be made that consider the trade-off between survival gains and toxicities. Utilities provide a means of linking duration of survival with quality of survival. Currently NCIC-CTG trials with an economic component only consider survival. There is no mechanism to include HRQOL or patient preferences.
2. Utility measures are important for decision makers. Decision makers are looking for local data that can provide important information for decision making that is directly relevant to the Canadian situation. Further, utility measures provide a means by which comparisons can be made between different treatment interventions across a variety of malignant and non-malignant diseases, a factor that is also important for decision makers in Canada. As the premier cancer clinical trials group in Canada, the NCIC-CTG alone can provide Canadian data in this area.
3. The NCIC-CTG has an opportunity to contribute to a new area of clinical trials research is lagging behind in this area. Earle et al¹ recently published a systematic review of utility research in cancer clinical trials and noted that utility research is increasing. However, Canadian contributions are notably absent at the present time. As a premier cooperative clinical trials group on the international stage, it is important for the NCIC-CTG to be current with the state of the science in this area. In fact, the NCIC-CTG is in a position to become a leader in this area, as it has been in the area of measurement of HRQOL within cancer clinical trials.

In summary, the Task Force agreed unanimously that the NCIC-CTG should introduce utility assessment into selected clinical trials. The science in the area is growing and the NCIC-CTG is well positioned to make a valuable contribution to the development of the science. As well, it is an area of research where Canadian-specific data is essential for decision making relevant to the Canadian situation. The NCIC-CTG can, and should, take a lead in collecting this data. Further, it is in a position to become a leader in the area for relatively little extra cost.

For NCIC-CTG to include utility measures in some of its trials requires that patients either be interviewed or administered a questionnaire to determine their valuation of health states arising in the context of a particular trial. This can be complex, time consuming and invasive of the patient's comfort and time. Hence, it is unlikely that NCIC-CTG would seek to gather utilities in all trials. Guidelines for selecting those trials that should incorporate utility assessment might include the following, as suggested by Drummond:

A Cost Utility Analysis might be considered when:

- health-related quality of life is the predominant outcome or a very important outcome of interest;
- it is important to have a common unit of outcome that combines the effects of morbidity and mortality;
- different health programs must be compared.

A Cost Utility Analysis is less likely to be valuable when:

- only intermediate outcomes are available, such as the changes in PSA level following treatment for prostate cancer rather than the long-term survival of the patients;
- effectiveness data shows the arms of a trial are equivalent in all of the outcomes, or shows that the trial arm is superior to the control arm both in having greater benefits

and lesser costs (in the first case, it is evident that the least costly intervention should be selected and in the second case the “dominant” strategy is clearly preferred);

- the extra cost of securing utility data is not itself cost effective.

3.2 Can current instruments to measure HRQOL be converted into utilities?

The question as to whether one of the HRQOL instruments currently used by the NCIC-CTG can be converted into utilities was addressed. If this were possible, it would offer flexibility in that it would then be possible to go back and derive utilities for those studies in which HRQOL was measured. (For example, if an economic evaluation of an ongoing study was thought to be warranted, the conversion of HRQOL measures from the trial -- such as the EORTC QLQ C-30 -- into utilities would be an efficient strategy.) Several researchers have explored the possibility of doing this. However, the Task Force unanimously agreed that the state of the science does not yet allow for adoption of this method. It was, nevertheless, considered important to keep abreast of developments in this area.

3.3 Which methods of measuring utilities should be used?

Utilities can be measured by either direct (sections 3.3.1 and 3.3.2) or indirect (sections 3.3.3) methods. Direct methods can be applied within a trial (section 3.3.1) or outside of a trial (section 3.3.2).

3.3.1 Direct methods within a clinical trial

The direct methods include the use of a visual analogue scale (VAS), time trade-off technique (TTO), and the standard gamble. In general, the optimal method depends on the type of decision problem at hand. The visual analogue scale, for example, is promoted when a decision involves comparing two treatment options with competing HRQOL considerations (e.g., mastectomy vs. breast-conserving therapy) because it allows holistic judgments as to the quality of both outcome states. The method, however, has been shown to be the least reliable of the three direct approaches, and often yields systematically different utilities.

The time trade-off method is used to establish a subject’s willingness to trade-off quality of life against the length of life. The respondent is asked whether she would prefer an imperfect health state over a certain period of time, or perfect health over a shorter period of time. The method then searches for the time point in perfect health at which the respondent is indifferent in her preference. The length of time that the respondent is willing to trade-off is therefore a measure of the disutility of the imperfect health state; the less the respondent values the imperfect health state, the more time she is willing to trade.

The standard gamble represents, in many authors’ opinions, the “gold standard” of utility assessment methods. It has earned this reputation because it is based explicitly on the axioms of rational decision-making borrowed from economic theory. In the method, the respondent is asked to consider an imperfect health state. She is then asked whether, in order to obtain a state of perfect health, she is willing to accept a certain risk of immediate death. In other words, the risk of death has to be acceptable to the patient in order to gain a better health. By varying the chance of certain death, the respondent’s point of indifference is searched for; that is, the chance of dying at which she values both options equally. The technique yields a utility value on the imperfect health state – the less she values that state the more willing she would be to risk immediate death in order to gain perfect health.

Both the standard gamble and the time trade-off suffer from limitations and potential biases. In both methods, the magnitude of the generated utility depends on whether perfect health, or health prior to the cancer diagnosis, is used as the anchor state. Research has also shown, for example, that the framing of the outcomes will influence respondents’ judgments, as will the level of detail of describing the health states for those who have not actually experienced them. The time trade-off will be influenced by the time horizon used for the imperfect health state (a

substantive problem in oncology when timeframes are often difficult to predict and sometimes distressingly short).

Advantages of the direct methods are that they:

- are considered to be the gold standards;
- they generally yield utilities that are considered to be the most sensitive;
- can eventually lead to creation a 'bank' of utilities related to specific disease states;
- can make an important contribution to the clinical research literature;
- may allow us to further explore the relationship between HRQOL and utilities.

Disadvantages of the direct methods are:

- there is a heavy burden on patients and staff;
- the method will not be representative of the general population, despite being more sensitive;
- there is a high financial cost;
- there is a high level of training required;
- obtaining agreement from all centres and their continued compliance is problematic, but without it, the methodological rigor is compromised;
- there is a risk that the high burden on patients and staff may jeopardize the smooth operation of the larger study.

In summary, for the reasons given above, the direct method within a trial is generally not recommended except perhaps in rare circumstances.

3.3.2 *Direct methods outside of a clinical trial*

The previous discussion of direct methods applies here as well. However, in this situation the method is applied outside the trial in question. That is, when the trial is complete, information from the HRQOL and symptom assessment obtained during the trial are used to create scenarios that describe the health state of patients receiving the treatment. The SG or TTO method is then used with a different group of subjects. Subjects might be patients who are potential recipients of this treatment under study, family members of patients, or members of the general public. The most appropriate 'subject' is a matter for discussion, with good arguments for or against each. If the direct method outside a clinical trial is used, a mix of patient and public is most often used.

The advantages of this approach in comparison to the direct method within a clinical trial area:

- it is far more efficient. One or two sites can become centres for conducting utility studies. This would minimize the intensive training and ensure standardization in the application of the method;
- it may be less costly than within the trial;
- if the trial yields a negative result then the unnecessary additional burden of assessing utilities can be avoided;
- it eliminates the risk of jeopardizing the smooth operation of the larger study.

The disadvantages are:

- it is less accurate and potentially less sensitive because it requires homogenizing the experience of patients within the trial into a description of the disease state and then communicating the description of that disease state as a 'scenario';
- it cannot be done until the trial is over;
- it may be less persuasive for policy makers.

3.3.3 Indirect method within a clinical trial

In comparison to the direct methods, the indirect methods require patients to complete questionnaires from which scores for specific health states can be derived. The responses to these questionnaires are given a value based on a previously determined scoring algorithm. These algorithms are developed from values of potential health states obtained from previous studies using direct methods.

There are a number of available questionnaires that are indirect methods for eliciting utility values. Of these, two are the most commonly used in clinical trials settings: the Health Utilities Index (HUI) and the EQ-5D.

The HUI was developed in Hamilton Ontario originally for use in a paediatric population. There are 3 versions of the HUI -- Mark 1, Mark 2 and Mark 3. Mark 1, which contains four dimensions of health status, is no longer being used in economic analysis. (See www.fhs.mcmaster.ca/hug and Appendix B-1)

Mark 2 has been the most commonly used version and has seven dimensions; sensory, mobility, pain, fertility, emotion, cognition and self care. Mark 2 was initially designed for use in childhood cancers, though it has since been extended to other disease areas. A scoring formula is available for Mark 2. The scoring formula involves assignment of utility scores for each dimension which are then combined based on a multiplicative formula. Scores were based on responses from a random sample of parents in Hamilton, Ontario.

Mark 3 is the latest version of the HUI and has eight dimensions: pain, emotion, cognition, ambulation, dexterity, speech, vision and hearing. A scoring formula for Mark 3 is available though it has not been subject to the peer review process. Scores were based on responses from a random sample of adults in Hamilton, Ontario.

The validity and reliability of both Mark 2 and Mark 3 versions of the HUI has been documented. Both Mark 2 and Mark 3 can be scored based on the same questionnaire. This questionnaire can take up to ten minutes to complete.

The EQ-5D (formerly the EuroQoL) (see www.euroqol.org and Appendix B-1) was designed by a group of European researchers. It provides a simple descriptive profile containing five dimensions (each of three levels); mobility, self care, usual activity, pain/discomfort and anxiety/depression. Various scoring formulae for the EQ-5D have been published though the most commonly used relates to values obtained from a random sample of 3000 adults, representative of the UK general population. The relative simplicity of the EQ-5D is deliberate in that it is designed to complement other HRQOL measures (see section 1.2) such as the SF-36.

The EQ-5D has been shown to be both reliable and valid. It takes at most two minutes to complete.

The choice between the EQ-5D and the HUI should be made on a study-by-study basis. The EQ-5D has some inherent advantages in terms of ease of completion and external validity of its scoring algorithm. However, given its broader coverage of dimensions of health, the HUI may be more responsive than the EQ-5D. Where possible, additional research relating to the appropriateness of available instruments in cancer related evaluations should be addressed.

Other questionnaires for utility elicitation are available. The Quality of Well Being Scale (QWB) was developed prior to both the EQ-5D and the HUI. However, the QWB is now used infrequently primarily due to the burden on respondents and the lack of a theoretical basis for its scoring systems. Other instruments are in development that may become appropriate for use in economic analysis: the Assessment of Quality of Life Scale (AQoL), the 15D scale and a utility scale based on the SF36.

The advantages are:

- they take a few minutes to complete and, therefore, there is a minimum of respondent burden;
- they are self-reported and therefore do not place a burden on the personnel conducting the trial.

The disadvantages are:

- instruments are less sensitive than direct methods.

4.0 Some Methodological Issues

It was recognized that there are methodological and other issues related to the measurement of the utilities. A brief discussion of some of these follows:

1. Opposition against measuring utilities arises because of the confusion that the same issues are addressed by measures of HRQOL.

⇒ Utilities are a measure of the strength of preference between health states. The state of the science in moving from HRQOL to utilities is still in its infancy and, therefore, a measure of HRQOL cannot yet be translated into a utility. Utilities introduce issues of patients' preferences and morbidity and complement, but do not replace, measures of HRQOL.

2. From whose perspective should the utility be measured?

⇒ This is an important philosophical question that remains highly controversial. Within the field of decision-making, controversy remains regarding the most appropriate group from whom utilities should be elicited. Possibilities include patients themselves, family members, health care workers or the general public. Some advocates suggest that only patients truly understand the disease and treatment experience. This is probably most relevant when the focus of the study is on the trade-offs patients themselves face. Advocates for using the general population stress the importance of overall population outcomes, particularly with regard to health policy decision-making. This controversy will not be resolved here.

3. What happens if there is no HRQOL in a study?

⇒ If it is decided that HRQOL will not be measured in a particular study, then there should not be a utility assessment in that study either. During the development of a trial, the trial developers should justify why they are not planning to include a utility assessment. This decision is directly linked to whether an economic evaluation is appropriate and whether measuring HRQOL is appropriate. The trial developers should liaise with the WGEA and the HRQOL regarding these issues.

5.0 Recommendations

1. NCIC-CTG should continue its international leadership role in clinical trials research methodology by becoming a leader in furthering the science of integrating utility assessments into clinical trials.
2. Trials with an economic component should incorporate a utility assessment unless a convincing argument is presented against this.
3. Trials with the potential of a post hoc economic component should be identified and the possibility of including a utility assessment should be considered.
4. Trials where HRQOL is considered an important outcome should consider including a utility assessment measure. This can be achieved with a low burden indirect measure.
5. The most appropriate utility measure should be determined on a trial-by-trial basis. Generally, an indirect utility assessment (e.g., HUI or EQ-5D) is the most appropriate. In certain instances direct utility assessment outside the trial maybe appropriate. Rarely, direct measurement within a trial may be necessary.

6.0 Next steps

6.1 Review of the Issue by NCIC-CTG Committees

1. This report will be distributed to the Chairs of the QOLC, WGEA and Dr. Pater. (Completed)
2. The report will be distributed to members of the respective committees before the Fall 2001 meeting of the NCIC-CTG. (Completed)
3. A joint meeting of the QOLC and WGEA will be held at the Fall 2001 meeting where the recommendations on utilities will be discussed and refined. (Completed)
4. Revisions made and redistributed. (Now in final draft form)
5. If it is endorsed by both the QOLC and WGEA (to be reviewed at the spring meeting, April 2002), it will be sent to the Clinical Trials Committee meeting.

6.2 Possible Introduction of Utilities into NCIC-CTG Trials

If the Clinical Trials Committee approves the concept of introducing utilities into its Cost Effectiveness Analyses and its Quality of Life Analyses, then we should proceed in a step wise fashion to select one or more trials where Cost Utility Analysis is particularly appropriate, the burden of gathering utility data is moderate, and the time to analysis of the trial is comparatively short. These trials can provide an assessment of the ongoing feasibility of Utilities in NCIC CTG trials.

WGEA and QOL should run one or more sessions for investigators on the concept, method and practical issues in application of utilities in a Cost Utility Analysis.

7.0 References

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9.0 Appendices

- A. Joint WGEA/QOLC task force members
- B. Indirect measures of utilities
 1. EQ-5D
 2. Health Utilities Index (HUI)

Appendix A

Joint WGEA/QOLC Task Force Members

- Heather-Jane Au, Cross Cancer Institute, Edmonton
- Michael Brundage, Kingston Regional Cancer Centre
- Doug Coyle, Ottawa Health Research Institute
- Eva Grunfeld (Chair), Ottawa Regional Cancer Centre
- Karen Somers, NCIC-CTG
- Hugh Walker, NCIC-CTG

Appendix B-1 EuroQol classification system¹

Mobility

1. No problems walking
2. Some problem walking about
3. Confined to bed

Self-care

1. No problems with self-care
2. Some problems washing or dressing self
3. Unable to wash or dress self

Usual activities

1. No problems with performing usual activities (e.g. work, study, housework, family or leisure activities)
2. Some problems with performing usual activities
3. Unable to perform usual activities

Pain/discomfort

1. No pain or discomfort
2. Moderate pain or discomfort
3. Extreme pain or discomfort

Anxiety/depression

1. Not anxious or depressed
2. Moderately anxious or depressed
3. Extremely anxious or depressed

Note: For convenience each composite health state has a five digit code number relating to the relevant level of each dimension, with the dimensions, always listed in the order given above.

Thus 11223 means:

- 1 No problems walking about
- 1 No problems with self-care
- 2 Some problems with performing usual activities
- 2 Moderate pain or discomfort
- 3 Extremely anxious or depressed

1 Drummond MK, O'Brien B, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes 2nd edition. Oxford University Press; 1997:163-164. For more information and scoring system visit website www.euroqol.org

Appendix B-2

Health Utilities Index mark 3 classification system²

Attribute	Level	Level description
Vision	1	Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.
	2	Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses.
	3	Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.
	4	Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.
	5	Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.
	6	Unable to see at all.
Hearing	1	Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
	2	Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
	3	Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people with a hearing aid.
	4	Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
	5	Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
	6	Unable to hear at all.
Speech	1	Able to be understood completely when speaking with strangers or friends.
	2	Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.
	3	Able to be understood partially when speaking with strangers or people who know me well.
	4	Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.
	5	Unable to be understood when speaking to other people (or unable to speak at all)

² Drummond MK, O'Brien B, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes 2nd edition. Oxford University Press; 1997:168-169.

For more information (e.g., mark1 and mark2 versions) visit website www.fhs.mcmaster.ca/hug

Health Utilities Index mark 3 classification system – con't

Attribute	Level	Level description
Ambulation	1	Able to walk around the neighbourhood without difficulty, and without walking equipment.
	2	Able to walk around the neighbourhood with difficulty, but does not require walking equipment or the help of another person.
	3	Able to walk around the neighbourhood with walking equipment, but without the help of another person.
	4	Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood.
	5	Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
	6	Cannot walk at all.
Dexterity	1	Full use of two hands and ten fingers.
	2	Limitations in the use of hands or fingers, but does not require special tools or help of another person.
	3	Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).
	4	Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools).
	5	Limitations in the use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools).
	6	Limitations in the use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).
Emotion	1	Happy and interested in life.
	2	Somewhat happy.
	3	Somewhat unhappy.
	4	Very unhappy.
	5	So unhappy that life is not worthwhile.
Cognition	1	Able to remember most things, think clearly and solve day to day problems.
	2	Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.
	3	Somewhat forgetful, but able to think clearly and solve day to day problems.
	4	Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.
	5	Very forgetful, and have great difficulty when trying to think or solve day to day problems.
	6	Unable to remember anything at all, and unable to think or solve day to day problems.
Pain	1	Free of pain and discomfort.
	2	Mild to moderate pain that prevents no activities
	3	Moderate pain that prevents a few activities
	4	Moderate to severe pain that prevents some activities
	5	Severe pain that prevents most activities