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The measurement of quality of life in hypertensive patients: a practical approach

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Introduction

The term 'quality of life' (QL) means different things to different people, with difficulty in deciding what should be included in an assessment of the subject. Having selected the areas to be covered, the measurements of these must be appropriate to the condition and its treatment, for example general profiles such as the Sickness Impact Profile (SIP, Bergner *et al.*, 1981) and the Nottingham Health Profile (NHP, Hunt *et al.*, 1986) describe limitations in lifestyle due to ill-health, such as loss of self care and mobility. These would not be appropriate for the majority of hypertensive patients who are free of symptoms prior to diagnosis and may experience only the possible psychological effects of labelling (McDonald *et al.*, 1985) and the adverse effects of drug treatment. However in a long term study, a proportion of hypertensive patients will suffer stroke or develop heart disease with consequent loss of dependence, and in this situation, these questionnaires (SIP, NHP) would be appropriate. In this paper we will consider only the measurement of QL in short-term trials (< 1 year) of antihypertensive treatments.

The measures involved in the assessment of QL, like any measure, need to be valid, repeatable, and capable of change (responsive) in order to detect any difference in QL occurring as a result of treatment or when comparing treatments. The questions should be acceptable to the patient. Such measures have been employed in randomised double-blind controlled trials to assess different antihypertensive treatments and we describe one self-administered questionnaire fully so that it can be employed by any researcher with the necessary interest and facilities.

Areas covered by the questionnaire

The questionnaire covers symptomatic (physical) well-being, psychological well-being and perception of the effects of antihypertensive treatment on lifestyle. These are considered to be the three areas most important to the hypertensive patient. The questionnaire does not include a measure of positive well-being, such as vitality or other areas such as social participation, performance and satisfaction at work. Objective tests of cognitive function are also not included but should be performed when there is real concern about the effect of a drug in this area. These methods will require a trained interviewer. An impairment in cognitive function may impair QL but only if the patient is aware of the problem. A self assessment of cognitive function is included in the questionnaire.

The questionnaire has three sections:

Symptomatic enquiry

This section asks about the two symptoms associated either with a high blood pressure or treatment, headache and nocturia, and a variety of other symptoms that may occur as side effects of drug treatment. These side effects cover many systems and as new drugs are introduced, new side effects are reported and questions have to be devised and included as appropriate. Many of the questions have been published (Bulpitt *et al.*, 1974, 1976) and the symptom questionnaire is suitable for patients on diuretics, β-adrenoceptor blocking drugs, calcium channel blockers, angiotensin converting enzyme (ACE) inhibitors and centrally acting drugs. The format is one requiring YES/NO answers and the

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questions are presented in this format as they have known validity and repeatability and have previously been shown to detect side effects.

We do not employ visual analogue scales (VAS) owing to the difficulty of explaining the concept to many patients, the lack of data on validity and repeatability, and the difficulty of interpreting the results. It is easier to report the percentage of patients who develop a symptom and for the reader to understand this concept, than to explain a mm change on an analogue scale. The symptom questionnaire is given in Appendix A.

Psychological well-being

Kellner & Sheffield (1973) developed the Symptom Rating Test (SRT) to measure the effects of psychotropic drugs on mood in psychiatric patients. Responses to 37 questions provided scores for separate sub-scales for depression, anxiety, somatic problems and inadequacy. It was subsequently modified to replace the inadequacy score with questions on cognitive function and hostility. Full details of the SRT are available from the authors (Kellner, 1983). As its name suggests, a limitation of the SRT, when used with hypertensive patients, is that it is symptom based; there may therefore be no distinction between the pharmacological side effect of a drug and the symptom of disturbed mental state, for example, dizziness may be a treatment side effect but would contribute to the anxiety score. As an alternative we are now also employing the Profile of Mood States (POMS, McNair *et al.*, 1971); this measures mood by a list of adjectives *not* symptoms and includes a measure of elevated well-being. Our comparisons of POMS and SRT are not yet complete and we currently recommend the SRT as we have shown this to be useful in hypertensive patients.

Activity

Questions on the effect of treatment on lifestyle together with responses to other questions (Appendix B) are used to score states of disability modified from the work of Fanshel & Bush (1970), (Bulpitt, 1982). The questionnaire scores disability as a Health Index on a continuum from 0 (death) to 1 (perfect health) (Table 1). The inclusion of a Health Index in a trial is most important as it allows patients to be included in the analysis even if they default, or cannot complete further questionnaires due to ill-health. As we are considering hypertensive patients the questionnaire in Appendix B mainly describes

Table 1 Scores for states of well-being in a health index

Health state	*Score*
Total well-being	1.0
Minor dissatisfaction	0.975
Discomfort	0.875
Minor disability	0.8
Major disability	0.75
Disabled	0.625
Confined	0.375
Bedridden	0.125
Isolated	0.025
Comatose	0
Dead	0

states of health better than 'confined'. It is assumed that the investigators can identify poor states of health such as being bedridden from their knowledge of the patient. The scoring of the Health Index is given in Appendix C and indicates how information from the Symptom data is employed to distinguish between the states of minor dissatisfaction and discomfort. The numerical values given to states of disability are controversial. A well known index of disability and distress, developed by Rosser & Kind (1978), includes negative values representing states worse than death, for example being in pain in an intensive care unit. The statistical methods used to derive scores include time trade off and standard gamble techniques. The scores in Table 1 are best considered as a time trade off, whereby subjects are asked how many of their remaining years of life they are willing to trade, for example to exchange being confined to the house for a return to perfect health. If they are willing to lose 62.5% of their remaining years – this gives a score of 37.5% or 0.375 when expressed as a proportion.

Another important use of the Health Index is that it can be employed in conjunction with survival data to give Quality of Life adjusted years of Survival or QALYS (Drummond *et al.*, 1987). For example, if one treatment leads to a mean survival of 5 years of perfect health and one to 5 years of health at a score of 0.8, the first treatment gives 5 QALYS and the second 4 QALYS. If the two treatments cost the same then the first is obviously to be preferred, yet this may not be true if treatment 1 is more expensive. QALYS are presently costed to help in discussions on the allocation of resources, but their use in this context needs to be carefully considered. For example, calculation of QALYS in short term trials makes certain important assumptions, e.g. both drugs have a similar effect on survival.

Table 2 Characteristics of a good question

1. Unambiguous
2. Uses no difficult words and is easily understood
3. Provides a truthful answer
4. Always completed
5. Answers one point only
6. Covers either a specified duration of time or just the present moment
7. Grammatically correct
8. Necessary
9. Repeatable

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Moreover the change in QALYS will depend on the scores or weights given to the different states of disability. If two drugs are compared in the same trial, the scores will indicate which is to be preferred, but if a comparison is made between results from difference health indexes in different trials, problems will arise if the QALYS are compared or costed.

Validity of the questionnaire

The validity of a measure is the extent to which the measure assesses what it is supposed to assess. When assessing well-being from the subject's point of view, we rely on his or her response to our questions. The face validity of a method therefore depends on the questions being understood and the answers being truthful. In this context, it does not matter whether the investigator agrees, but only that the subject answers with the truth as he or she sees it. For full comprehension the questions should have the characteristics listed in Table 2. Validity will be enhanced if the question is unambiguous, does not use 'difficult', e.g. medical words, and can be answered by the subject. Asking a patient if he or she has suffered from hypotension is both unlikely to be understood and the answer may not be known. Validity is more likely to be present when the question covers only one point and a specified time interval, and is repeatable. To discover the 'truth' the question should not suggest the answer or have an obvious morally correct response. In addition the question should be administered by a neutral method, as the relationship of a patient to an investigator may distort the results. For example, the patient may be grateful to the doctor and report more favourably on his or her well-being than otherwise. The safest neutral method is a self-administered questionnaire, at least for those who are literate in the language used and who have remembered to bring their reading glasses. The questions given in the Appendices have high individual response rates.

Validity may be determined by reference to an external standard. For example, the questions on light headedness are related to the fall in blood pressure on going from the lying to the standing position (Bulpitt *et al.*, 1974). The Symptom Rating Test was validated by comparing the results of a study in depressed patients and controls with the results of psychiatrists' ratings using the Hamilton Depression Rating Scale (Fava *et al.*, 1982). SRT scores were also correlated with the concentration of benzodiazepines measured in the blood of anxious patients. Higher levels of distress were associated with lower concentrations (Robin *et al.*, 1974). Evidence for discriminative validity for the Health Index was shown in a community based study in which hypertensives had significantly lower scores compared with their age, sex matched normotensive controls (Battersby *et al.*, 1989).

Repeatability of the questionnaire

A valid question is usually repeatable. Unfortunately, the converse is not necessarily true: a question may be repeatable but not valid and both validity and repeatability must be carefully assessed. Table 3 gives the percentage of 78 normotensive persons living in London complaining of nine symptoms included in a symptomatic enquiry (Bulpitt *et al.*, 1976). Also given is a measurement of repeatability after 10 months in the 71% of subjects who could be contacted at that stage. A total lack of reproducibility would score zero and perfect agreement, 1. The repeatability of the questions was judged to be acceptable.

Table 3 Percentage of 78 normal subjects complaining of symptoms and the repeatability of questions as estimated 10 months later

Symptom	*% Complaining*	*Repeatability*
Nocturia	45	1.00
Sleepiness	31	0.95
Nasal stuffiness	27	0.99
Vivid dreams	25	0.98
Dry mouth	21	0.98
Weak limbs	18	0.95
Blurred vision	15	0.99
Nausea	12	0.98
Poor mental concentration	6	0.99

The subjects were living in London and randomly selected from a population (general practitioner list) Bulpitt *et al.* (1976).

Responsiveness of the questionnaire

Responsiveness is the ability of the questionnaire to detect changes, for example, those that occur as the result of treatment. In drug trials there is little point in repeatedly measuring, say, personality when any such measure is most unlikely to change with treatment. The questions on symptomatic well-being discussed in this article are sensitive to the side-effects of pharmaceutical agents used in the treatment of hypertension (Bulpitt *et al.*, 1979). The assessments of anxiety using the SRT are known to respond to the effect of tranquillizers (Kellner *et al.*, 1979). Further evidence of responsiveness to the effects of anti-hypertensive drugs has accrued from use of the SRT in trials of different anti-hypertensive drugs. These results are discussed in detail in a later section. In summary the questionnaire's responsiveness is established as side effects are detected: an excess of symptoms on propranolol in comparison with verapamil (Fletcher *et al.*, 1989a); an increase in depression on methyldopa when psychological well-being was assessed (Fletcher *et al.*, 1990 submitted for publication); and an increase in the Health Index when verapamil was compared with propranolol (Fletcher *et al.*, 1989a). The latter improvement was due to both an improvement in symptomatic well-being and an increase in activity with fewer days off work on verapamil.

Standardization of methods

When attempting to diagnose diabetes mellitus, the clinician knows how to standardise the methods employed. For example, blood sugar must be measured fasting or an exact time after a given glucose load and it is important to standardise the type of blood sampled, venous or capillary, and the site of blood sampling. Finally the laboratory method for measuring blood glucose must have an acceptable precision and repeatability. When measuring QL the same problems of standardisation arise. The patients should provide the information in response to a self-administered questionnaire or directly to an interviewer who asks an exactly defined question. A third party should not be consulted and therefore the patients must give their responses in a quiet area without the possibility of interruption. This is best provided in a separate room, the patients giving their answers before seeing any medical staff. In this situation they will not be able to consult their family, nor will they be influenced by such factors as knowledge of their current blood pressure, or need for an increase in tablets.

Whether it is better for a questionnaire to be administered by an interviewer or self-completed depends on the complexity and difficulty of the interview, the health status and literacy of the subject, the skills of the interviewer and costs and other practical considerations. Self-administered questionnaires are most commonly used in large multi-centre trials where training, standardising, and deploying interviewing staff may not be feasible. A researcher or medical practitioner may not be the best interviewer, since they are likely to inject considerable bias, albeit unconsciously, into the interview process. In a single-blind European trial of antihypertensive therapies, the questionnaires were designed to be completed by the patients, but in fact 50% were administered by the patient's physician. Although the responses and psychological well-being were similar in the self-assessed and doctor assessed groups at the start of the trial, the results at the end of the trial showed a

considerable discrepancy. Using the data from the self-administered questionnaires, both drug groups showed an improvement after 3 months' treatment, but the fall in the symptom complaint rate was significantly greater in patients treated with an angiotensin converting enzyme (ACE) inhibitor than a centrally acting drug (Fletcher *et al.*, 1989b). The physician-assessed group showed a different pattern of results; patients on the centrally acting drug showed deterioration in most areas, while those on the ACE inhibitor showed considerable improvement. These data suggest bias owing to the physicians' expectations of the effects of a drug and highlight the unreliability of assessment of quality of life in single-blind or open trials. The nature of the reporting of effects of treatment, and the desire of the patient to please the physician, seen as a giver-of-care, has frequently been discussed.

Acceptability of the questionnaire

The questionnaire when self-administered, has proved acceptable to a large number of patients. They have been willing to complete it on up to four occasions taking between 20 and 40 min. Patients usually welcome the opportunity to provide information on the effect of being ill on their everyday lives especially if they are otherwise unoccupied, such as while waiting for laboratory tests and clinical examinations. However, consideration must be given to the patient's state of health and no extra burden placed on them.

Trial design

As indicated above, QL measures must be made in a randomized double-blind trial. Experience to date has mainly been with parallel group trials as the duration of a QL trial may make it difficult to cross over without carry over effects. For example, if taking on β-adrenoceptor blocking drug interferes with exercise capacity, it will take time for the patient to realize this and even longer to adjust his or her life-style, for example in stopping playing squash. Similarly, stopping the β-adrenoceptor blocker and an increase in exercise capacity will not be immediately followed by playing squash again. For these reasons, QL trials should ideally last for 4–6 months and if a cross over design is employed, carry over effects must be considered. It is important to make a baseline assessment on placebo or to include a placebo treated group so that all the symptomatic complaints are not attributed to the treatment of hypertension. QL trials should also include more patients than trials designed simply to assess anti-hypertensive efficacy. They will, however, be much smaller than trials designed to detect changes in mortality and morbidity. QL trials have to be large, usually 150–200 patients per treatment group owing to the variability of the data collected (see below). However, testing very pharmacologically different treatments have been successful in a smaller trial (Fletcher *et al.*, 1989a).

Statistical analysis

The major outcomes of importance are the within-patient changes in total complaint rate, total Symptom Rating Score, the depression and anxiety sub-scales, and the Health Status Index. These changes are usually normally distributed and may be compared by parametric methods: unpaired *t*-tests to compare two drug treatments and analysis of variance to compare more than two. Non parametric methods may also be employed with little loss of sensitivity and are desirable in the presence of 'outlying' results. Other analyses of interest are whether, within drug groups, the changes are statistically significant. This may be tested for using a paired *t* test. However this change is often due more to the effect of entering the trial than taking the particular drug treatment (discussed below).

Randomisation is expected to result in the different groups having similar characteristics at baseline. However, and unusually, differences in baseline characteristics may occur. If the patients differ in baseline characteristics for the end-points examined, for example one group having a higher depression score than the other, then changes in depression score may depend on initial score by the 'regression to the mean' phenomenon (Bulpitt, 1983). In other words the more 'depressed' group may have the greater potential for improvement. In this situation, the most simple solution is to present the changes in depression score according to various stratified levels of initial score. Should one drug consistently provide large falls in 'depression' score when the data are stratified in this way, this produces persuasive evidence for a true between drug difference. In addition the analysis of variance (ANOVA) may be extended to an analysis of covariance, the baseline variables acting as covariates. Should the groups not differ importantly in baseline variables, then analysis of co-variance or stratified analysis is usually unnecessary.

Table 4, gives the observed standard deviation for the within patient changes from different

Table 4 The average standard deviation of within patient changes and range of standard deviation in three trials using the questionnaire, verapamil against propranolol (Fletcher *et al.*, 1989a), captopril against atenolol (Fletcher *et al.*, 1990), and pinacidil against nifedipine (Fletcher & Bulpitt, 1989). The average s.d. is the unweighted mean of within patient change in results on the six drugs

	Average s.d.	*Range of s.d.*
Symptom complaint rate	11.2	7.4–13.6
Total score (SRT)	8.7	4.7–12.3
Depression score (SRT)	2.2	1.2–3.1
Health Index	9.8	8.4–11.9

trials which can be used to calculate the numbers required for a trial to compare two drugs. The hypothesis to be tested varies with the measure of QL and the drug, for example it may be postulated that one treatment produces symptoms, or is associated with a relative deterioration in depression score. The calculation must be made for a given power and level of significance. The power of the study is the level of confidence in the result of *no difference between* the drugs. For example to compare one drug, associated with a fall in symptom rate of 3 units with a second where side effects cancel out the usual improvement due to entering the trial to give zero change; 250 patients are required on each treatment (s.d. 11.2, 1-β = 90%, α = 5%).

As only five main effects are to be examined it may be suggested that the problem of assessing multiple end points be ignored. This advice is not based on statistical grounds but on the fact that most trials of efficacy or biochemical effects do not traditionally adjust for having say, standing and lying systolic and IV and V diastolic pressures as six end points. Commonsense dictates that these are inter-related and expected to change together. Even when many tests are not closely inter-related, for example haematological changes, and biochemical changes of renal, hepatic and thyroid function, most authors will not adjust the level of significance for examining five or six end points. However, when many end points are considered, such as individual side effects, standard methods of adjustment should be used (Miller, 1966).

Results

Table 5 gives the baseline, end of trial and mean within-patient changes in five end points in three

Table 5 The baseline, and average within-patient change in results on six anti-hypertensive drugs compared in the three trials considered in Table 4. A negative result indicates an improvement except for the Health Index when a positive value indicates an improvement

	Trial 1				*Trial 2*				*Trial 3*			
	Verapamil		*Propranolol*		*Atenolol*		*Captopril*		*Pinacidil*		*Nifedipine*	
	Baseline	*Change*	*Baseline*	*Change*	*Baseline*	*Change*	*Baseline*	*Change*	*Baseline*	*Change*	*Baseline*	*Change*
Symptom complaint rate	33	−1.1	29	+6.4*	21	−3.1	18	−1.3	21	−2.0	24	−3.1
Total SRT score	18	−2.4	13	+1.7	10	−2.3	9	−1.4	15	−2.3	13	+0.1*
Depression	3.4	−0.3	2.6	0	1.6	−0.1	1.6	−0.4	2.7	−0.5	3.1	−0.2
Cognitive impairment	3.6	−0.2	1.9	+0.3	1.3	−0.3	1.6	−0.2	2.6	−0.4	2.8	+0.2*
Health Status Index	87	+2.1	88	−3.4*	87	0	90	+1.1	91	+1.1	89	+2.6

* $P < 0.05$ for a difference between the two drugs. The symptom complaint rate is the percentage of positive responses to the questions in Appendix A, Section 1.

trials comparing respectively verapamil with propranolol (Fletcher *et al.*, 1989a), atenolol with captopril (Fletcher *et al.*, 1990), and pinacidil with nifedipine (Fletcher & Bulpitt, 1989). Unfortunately we cannot report any results from long term placebo data, but assuming that anti-hypertensive drugs do not improve QL and only maintain it, it can be estimated that the trial or placebo effect is at least an improvement of 3.1 units in symptom complaint rate (observed with both atenolol and nifedipine), 0.4–0.5 units in depression score (observed with captopril and pinacidil) and 2.1–2.6 units in Health Status Index (observed with verapamil and nifedipine). A second assumption is that the drugs do not have any euphoriant, antidepressant or anxiolytic properties and the assumption that anti-hypertensive drugs do not improve QL may be reasonable in the short term but not in the long term when mortality and morbidity are prevented. The data suggest that propranolol causes a deterioration in symptomatic well-being and possibly increases depression. Similarly nifedipine may adversely affect self-reported cognitive function.

Conclusion

In the appendices we describe a questionnaire being employed in trials to estimate QL in the treatment of mild to moderate hypertension. For the assessment of psychological well-being the reader is referred to the manual of the Symptom Rating Test (Kellner, 1983). The content, validity, repeatability and responsiveness of the questionnaire is discussed together with standardisation of its use, its acceptability to the patients and the implications for the design of trials of antihypertensive drug treatment when QL is measured. The analysis of the questionnaire is discussed together with the results of its use in three randomised double-blind trials comparing different anti-hypertensive treatments.

Appendix A

Please tick the box ☑ or insert number where appropriate e.g. HOURS OF SLEEP [8]

Section 1

1. In the last month have you suffered from lightheadedness or faintness? YES ☐ NO ☐

   If NO, please go to question 4

2. *If YES*, does the lightheadedness or faintness occur only when you are standing? YES ☐ NO ☐

3. For how many hours in the day are you troubled by lightheadedness or faintness?

   Less than one hour ☐
   1–2 hours ☐
   More than 2 hours ☐

4. In the last month have you often felt sleepy during the day? YES ☐ NO ☐

5. How many hours per 24 do you usually sleep? ☐ HOURS

6. Have you in the last month noticed weakness in the limbs? YES ☐ NO ☐

7. Have you in the last month had blurring of vision? YES ☐ NO ☐

Please make sure you have answered all the questions on this page.

8. Do you get short of breath walking with people of your own age on level ground? YES ☐ NO ☐

9. Are your ankles swollen at the end of the day? YES ☐ NO ☐

10. Compared to other men and women of your age, do you tend to walk
    - Slower ☐
    - Faster ☐
    - About the same pace ☐

11. How often do you usually open your bowels?
    - Enter number of times per day ☐
    - *or* number of times per week ☐

12. Are your motions often loose or liquid? YES ☐ NO ☐

13. In the last month have you often been constipated? YES ☐ NO ☐

14. How many times, on average, do you rise at night to pass urine?
    - 0 ☐
    - 1 ☐
    - 2 ☐
    - More than twice (please indicate number of times) ☐

15. In the last month have you suffered from a dry mouth? YES ☐ NO ☐

    If NO, please go to question 17.

16. *If YES* does the dry mouth interfere with talking or eating? YES ☐ NO ☐

17. In the last month have you been troubled by a bad taste in the mouth? YES ☐ NO ☐

18. In the last month have you been troubled by a blocked or runny nose? YES ☐ NO ☐

19. Compared to other people of your age, are your powers of concentration
    - Better than average ☐
    - Same as average ☐
    - Worse than average ☐

20. In the last month have you felt flushing of the face or neck? YES ☐ NO ☐

21. Within the last month have you often been troubled by vivid dreams or nightmares? YES ☐ NO ☐

22. Within the last month have you often felt sick or vomited? YES ☐ NO ☐

23. Have you had a rash in the last month? YES ☐ NO ☐

24. Have you suffered itching in the last month? YES ☐ NO ☐

25. Do your fingers go white in the cold weather? YES ☐ NO ☐

    If NO, please go to question 27

Please make sure you have answered all the questions on this page.

26. If YES, do they become painful? YES ☐ NO ☐

27. Have you, in the last month, suffered from headaches? YES ☐ NO ☐

If NO, please go to question 30
IF YES, please answer question 28 and question 29

28. How often do your headaches occur?

1 or more per day ☐
1–6 per week ☐
Less than 1 per week ☐

29. At what time of the day do your headaches occur?

On waking in the morning ☐
During the day but not present on waking ☐
During the evening ☐

30. In the last month have you suffered from a dry cough? YES ☐ NO ☐

31. The next few questions relate to your sex life. While we appreciate that this information is of a very personal nature, we are interested in all aspects of your well-being and would like you to answer them. Again we would stress that this information is confidential.

Is your interest in sex

Less ☐
The same or greater ☐

32. Do you have sexual intercourse? YES ☐ NO ☐

If NO, please go to question 33.

If YES, please go to question 34

33. Is your reason for not having sexual intercourse (tick any box applicable)

Lack of interest ☐
Other reason related to your health (please specify) ☐

_____

_____

_____

Please go to Section 2

34. How often do you have sexual intercourse?

Please write in the box the number of
Times per week ☐
or Times per month ☐
or Times per year ☐

35. For men only

During sexual intercourse are you troubled by failure to sustain an erection? YES ☐ NO ☐

Please make sure you have answered all the questions on this page.

Appendix B

SECTION 2

36. Please tick the answer that best describes your situation.

In paid employment	☐
Not in paid employment but working round the house or looking after relatives	☐
Unemployed but looking for a job	☐
Unemployed for medical reasons	☐
Retired	☐

37. *If you ticked in paid employment*

How many days off work did you have due to ill-health, in the last month? Please write the numbers of days in the box, or write **none** if you had no days off due to ill health. ☐

If none, go to question 39

38. If you had days off work due to ill-health, what was the reason?

_____

_____

_____

39. During the last month have you been unable through ill-health to carry out your usual activities around the house and garden? YES ☐ NO ☐

If NO, please go to question 42

40. *If YES*, for how many days were you unable to carry out your usual activities through ill-health?

Please write number of days ☐

41. What were the reasons that you were unable to carry out your usual activities through ill-health?

_____

_____

_____

42. Do you have any hobbies? YES ☐ NO ☐

43. If YES, please can you list your hobbies

_____

_____

_____

Please make sure you have answered all the questions on this page.

44. Has your state of health interfered with these hobbies recently? YES☐ NO☐

If NO, please go to question 46

45. *If YES*, in what way?

_____

_____

_____

46. Has your state of health interfered with your life in any other way recently? YES☐ NO☐

If NO, please go to Section 3

If YES, in what way?

_____

_____

_____

Please go to Section 3

Please make sure you have answered all the questions on this page

{NOTE: Section 3 is the psychological well-being questionnaire}

Appendix C

Scoring of Health Index (Appendix B)

i) Disablement

Score 0.625 when 'unemployed for medical reasons' (Q36).

ii) Major disability

Score 0.75 when patient unable to go to work for more than 3 days in the last month (Q37) or to do usual jobs around the house for this period (Q39).

iii) Minor disability

Score 0.8 when high blood pressure or treatment interfered with hobbies (Q44) or life (Q46).

iii) Discomfort

Score 0.875 when not allocated to one of the above activity states yet, on average, the patient had more than 30% positive answers to the qualitative questions on symptoms (Q1–30).

Minor dissatisfaction. Score 0.975 when not allocated to any of the above activity states and the patient had less than 30% positive answers to the questions on symptoms.

The score recorded is the lowest of the above scores. Please note, if patient has died, score 0; confined to bed, score 0.125; and confined to the house but not to bed, score 0.375.

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