1990

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DOI: <https://doi.org/10.31979/etd.er2w-7sw5>
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of life questionnaire designed for hypertensive patients**

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San Jose State University, 1990

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**Study to Estimate the Content Validity and
Reliability of a Quality of Life Questionnaire
Designed for Hypertensive Patients**

**A Thesis
Presented to
the Faculty of the Department of
Human Performance
San Jose State University**

**In Partial Fulfillment
of the Requirements for the Degree
Masters of Arts**

**by
Carla Botelho Sottovia
December 1990**

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ABSTRACT

STUDY TO ESTIMATE THE CONTENT VALIDITY AND RELIABILITY OF A QUALITY OF LIFE QUESTIONNAIRE DESIGNED FOR HYPERTENSIVE PATIENTS

by Carla B. Sottovia

This study tested the content validity and reliability on a new quality of life questionnaire. Thirty-nine hypertensive male patients ranging in age from 31-59 years were used as subjects. First, 20 experts evaluated the questionnaire for its content validity. They classified each question in one of the three domains of the quality of life spectrum: function, perception, and symptom. Factor analysis was used to further test the content validity of the questionnaire. The overall content validity of the questionnaire was poor. Several questions showed ambiguity in their interpretation and hence, should be reworded. Secondly, the questionnaire was given to each patient. Internal consistency (reliability) of the questionnaire was determined from the calculation of alpha coefficients on the questions related to each factor. The results of coefficient alpha analysis indicated high reliability for factors I, II, and V ($R = .93, .81, \text{ and } .76$, respectively). It was concluded that this questionnaire needed to be further retested before used in clinical trials.

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CHAPTER I

Introduction

This chapter is divided into the following sections: background for the study, significance of the problem, statement of the purpose, approach to the problem, null hypothesis, delimitations, limitations, operational definitions, and summary.

Background for the Study

Hypertension is a common disease in the western society, and the treatment of patients with this disease constitutes a major part of a physician's daily workload. It has been estimated that 24 million adult Americans have mild hypertension, defined as a diastolic blood pressure between 90 and 104 mmHg. The incidence of mild hypertension increases with age and is common in both men and women. In certain age groups, as many as 30% are effected by this disease. Because of its magnitude, hypertension is a major health problem in the United States (Wenger, Mattson, Furberg, & Elinson, 1984c).

Over the past 10 years, there has been a steady increase in the number of asymptomatic people with mild hypertension who have been treated with hypertensive drugs. People in the United States are affected more than any other country. The expanding treatment of these 20-25 million people unquestionably represents the most extensive use of drugs ever attempted for the prevention of a disease (Hyman & Kaplan, 1985). In treating patients with hypertension, physicians who are successful in controlling blood pressure may be unaware of the negative effect that anti-hypertensive drugs can have on the quality of life (i.e., physical, emotional, sexual, and social functioning) of their patients. Given the increasing array of anti-hypertensive drugs currently available, physicians are faced with many choices in selecting medications that are effective with limited side effects. The potential adverse affects of drugs on the quality of life of patients with cardiovascular disease are becoming more widely respected by health professionals (Croog, Levin, Testa, Brown, Bulpitt, Jenkins, & Klerman, 1986).

Significance of the Problem

Many studies have shown that hypertensive patients undergoing long-term drug therapy suffer adverse side effects affecting their quality of life (Bulpitt, Dollery, & Carve, 1974; Bulpitt, Hoffbrand, & Dollery, 1976; Bulpitt, 1982; Croog et al., 1986; Fletcher, & Bulpitt, 1985; Jachuck, Brierly, & Jachuck, 1982; Kidson, 1971). Ideally, a long-term, comprehensive evaluation of the effect of anti-hypertensive treatment on the quality of life should be used in a clinical therapeutic assessment (Wenger, Mattson, Furberg, & Elison, 1984a). However, most of the questionnaires available are not suitable since their indices depend only on performance and ignore symptoms and feelings. Other restrictions include primarily time constraints, a feasible study design, and the need for a highly trained staff to administer the tests (Wenger, Mattson, Furberg, & Elison, 1984b). A more reasonable approach is to develop a quality of life questionnaire assessment instrument specifically for use in a clinical setting. By designing a new assessment instrument for a specific purpose, the investigator gains precision of measurement at the cost of generalizing the results.

In creating a new assessment instrument, it is important to determine the reliability and validity of the assessment instrument (Wenger et al., 1984a).

Statement of the Purpose

The purpose of this study was to estimate the reliability and content validity of a new quality of life questionnaire developed by the Institute for Aerobic Research (Dallas, TX). This questionnaire was to be used in clinical trials with hypertensive patients undergoing long-term drug therapy.

Approach to the Problem

Thirty-nine hypertensive male patients undergoing long-term drug therapy were used as subjects. The subjects ranged in age from 31-57 years. First, 20 experts in the field of hypertension evaluated the questionnaire for its content validity. A factor analysis was used to further test the content validity of the questionnaire. Secondly, the quality of life questionnaire was given once to each patient in order to estimate its reliability. It was simple to administer, and it took into account the three

main components of the quality of life spectrum (functional capacity, perceptions, and symptoms). A coefficient alpha estimate was used to determine the internal consistency of all questions from each identified factor.

Delimitations

This study was delimited to 39 hypertensive patients who were involved in a 2-year study on the anti-hypertensive effects of fosinopril sodium, propranolol hydrochloride, and a program of aerobic exercise. The study was completed in June, 1989.

Limitations

The factors in this study which could not be controlled included:

1. Honesty of the subjects when answering the questionnaire.
2. Inability to control the changes that might have occurred in the quality of life of each patient which might have been due to factors other than the effect of drug therapy.

3. Unavailability of a larger sample of subjects to estimate content validity.

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Definition of Terms

Asymptomatic: A body condition that does not indicate illness (Hornby, 1975).

Clinical Trials: A controlled setting for testing under medical supervision.

Experts: Medical doctors and/or exercise physiologists who had been involved in previous studies with hypertensive patients undergoing long-term drug therapy or who were involved in the present long-term drug therapy study. All experts had administered quality of life questionnaires for at least two years or longer.

Hypertension: A disease defined as diastolic blood pressure of 90 mmHg or higher, or a systolic blood pressure greater than 140 mmHg (The 1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, 1984).

Quality of life - defined under three broad components:

- a) Functional capacity - daily routine,

social, intellectual, emotional, and economical.

b) Perception - health status and well-being (life satisfaction).

c) Symptom - disease under study and other illness (Wenger, et.al., 1984a).

Quality of Life Questionnaire: A questionnaire developed by the Institute for Aerobic Research (Dallas, TX) in order to test the quality of life of hypertensive patients undergoing long-term drug therapy.

Summary

This chapter included the introduction, background for the study, significance of the problem, statement of the purpose, approach to the problem, delimitations, limitations, definitions of terms.

CHAPTER II

Review of Literature

Introduction

"Mild hypertension is the prototype disease for the class of conditions in which the patient is ambulatory, usually asymptomatic, and feels well" (Wenger et al., 1984c). The diagnosis of hypertension in adults is confirmed when the average of two or more diastolic blood pressure checks on at least two subsequent visits is 90 mmHg or higher, or when the average of multiple systolic blood pressure on two or more subsequent visits is consistently greater than 140 mmHg (The 1984 report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, 1984). The incidence of mild hypertension increases with age and is common in both men and women (The 1984 report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, 1984). More than 60 million people in the United States have elevated blood pressure (140/90 mmHg or greater) or have been informed by a physician that they have

hypertension. This chapter included a discussion of quality of life and hypertension, measurement of the quality of life, effect of long-term drug therapy on the quality of life, and labeling.

Quality of Life and Hypertension

An important aspect of anti-hypertensive drug therapy that is often neglected by physicians, is its effect on the quality of life of their patients. Some patients perceive the use of anti-hypertension medication to be more troublesome than their symptomless disease (Croog et al., 1986). This results in noncompliance and ineffective long-term treatment.

Quality of life has been defined under three broad components: functions, perceptions, and symptoms (Wenger et al., 1984a). Functions include activities involved in daily personal functioning such as dressing, eating, meeting basic individual needs, and maintaining adequate physical activity. Involvement of social activities with friends, community interactions, family relationships, and marital satisfaction are other components of functional capacity.

Intellectual functions include memory and alertness, the ability to communicate, confidence in making decisions, and judgment. Manifestations of emotional status are mood changes, feelings of anger, guilt, hostility, depression, helplessness, sick-role behavior, satisfaction, expectations, fears, and concern about the future. A further dimension of the quality of life is the ability to maintain a satisfactory standard of living, determined by income, insurance coverage, job satisfaction, retirement benefits, and so forth. This dimension is significantly influenced by the overall functional capacity.

Perceptions are defined as an individual's view of his or her situation. This encompasses personal value judgments of the components. Of particular interest are perceptions of general health status, level of well-being, and satisfaction with life. Symptoms of the disease, per se, those induced by treatment or abolished by intervention, constitute the third major component of the quality of life. Symptoms will influence the other two factors, functional capacity and perceptions. In fact, all three are interrelated.

Measurement of the Quality of Life

Quality of life data provides an independent evaluation of the success, or failure of an intervention, and may be the deciding factor in the final selection of therapeutic alternatives when survival advantages between treatments do not differ or are marginal. In a clinical trial involving chronic therapy, no matter how successful the intervention, the effectiveness depends on long-term adherence to the therapy. Quality of life variables may help document attitudes, traits, and lifestyle changes that can influence compliance with a particular intervention (Wenger et al., 1984a). Ideally, long-term, comprehensive evaluation of the effect of anti-hypertensive treatment on the quality of life should include all three components discussed above; however, there are serious restrictions on utilizing this approach in a clinical setting. These include primarily time constraints, a feasible study design, and the need for a highly trained staff to administer the tests (Wenger et al., 1984a). Most of the questionnaires available are not suitable for use in a clinical therapeutic assessment (Wenger et al., 1984b). Many indices depend only on performance and

ignore symptoms or feelings. Also the validity, reliability, and sensitivity of these indices are variable, and may only identify gross dysfunction. Two well-known indices, the Sickness Impact Profile (SIP) and the Index of Well-Being, take into account performance, social activity, mobility, and emotional state and have been shown to have high reliability and validity (Bergner, Bobbitt, & Carter, 1981; Krauth, 1982). For instance, the SIP was developed to provide a measure of perceived health status that was sensitive enough to detect changes or differences in health status that would occur over time or between groups. It was designed to be broadly applicable across types and severities of illness and across demographic and cultural subgroups. The SIP was intended to provide a measure of the effects or outcomes of health care that could be used for evaluation, program planning and policy formulation. A large field trial on a random sample of prepaid group practice patients and smaller trials on samples of patients with hyperthyroidism, rheumatoid arthritis, and hip replacement were undertaken to assess reliability and validity of the SIP and also to provide data for category and item analysis. The results showed a high test/retest reliability

($R = .92$) as well as internal consistency ($R = .94$). The SIP contains 136 items in 12 categories. The major limitations of the SIP were its length and the lack of disease specific indices sensitive to treatment effects.

In addition, the Index of Well-Being (IWB) was based on objectively reportable facts that occurred on a given day over a 6-day period preceding the interview. It covers institutionalization, self-care, social activities and reports of symptoms and problems. Also, it incorporates social preferences for functional states (Wenger et al., 1984b). Further, the error characteristics of the functional state classification, as determined on the basis of data obtained from 1,324 subjects with all prevalence diseases and injuries were as follows: sensitivity, $R = .90$; specificity, $R = .99$; predictive value dysfunctional, $R = .95$; and predictive value functional, $R = .98$ (Kaplan, Bush, & Berry, 1976). Also, the test-retest reliability for final codes on successive days was high ($R = .98$). This included actual state changes between two days as well as any misclassification. The major limitations of the IWB were its complexity and the need of trained interviewers to administer it. It described the

patient's state at one point in time; additional data would be needed for estimating future quality of life. Like other instruments, the IWB questionnaire does not identify the cause of a change in a score (Wenger et al., 1984b). Since both of these indices assess fairly broad functional states, their ability to discriminate between more subtle changes produced by the disease state of treatment has been questioned (Wenger et al., 1984b). Thus, the use of an instrument designed to measure changes produced by a specific disease or treatment becomes essential. In summary, the SIP and IWB questionnaires lack disease-specific indices that are sensitive to a particular illness or treatment effects.

Effect of Long-term Drug Therapy on the Quality of Life

Long-term drug therapy can produce a wide range of side effects. These side effects may interfere with the enjoyment of food, sedentary hobbies, exercise, and sex. For instance, Bulpitt and Dollery (1973) investigated the side-effects of hypotensive agents evaluated by a self-administered questionnaire which was completed by 477 patients in a hypertension

clinic. The complaints of the patients were analyzed according to the type of therapy being given and the dose of drug taken. Methyldopa therapy was associated with sleepiness, weakness of the limb, sleeping longer at night, and rising more frequently at night to pass urine. Bethanidine administration was related to postural hypotension, impotence, and failure of ejaculation, and more frequent opening of bowels. The authors concluded that more research was required into symptoms and side-effects experienced by hypertensive patients. Furthermore, similar results were again found by Bulpitt et al. (1974) in a study investigating the quality of life of normotensive control subjects and patients taking anti-hypertensive agents. The study was conducted in three phases: a period of checking that patients understood the questionnaire, a survey of patients in the Hammersmith Hospital Hypertension Clinic, and a survey of normal subjects registered with general practitioners at a local health center. At phase I (a period of three months), every fifth patient attending the hypertension clinic was asked to complete the questionnaire while waiting in the clinic. At the ensuing routine interview, the questionnaire was examined and it was confirmed that

the patients had understood the questions by reviewing the answers given. At phase II (a period of two months), the patients who had not previously completed a questionnaire were selected to answer the questionnaire. At phase III, 231 patients were randomly selected from the age/sex register of a health center to answer the questionnaire (normotensive controls). The results showed that the treated hypertensive patients complained more of sleepiness, postural hypotension, dry mouth, nocturia, diarrhea, slow walking pace, impotence and failure of ejaculation, than did the normotensive controls. Headaches and depression were more common in women than men in all age groups. These two symptoms (headaches and depression) were reduced in the elderly. Black patients slept less than caucasian patients and complained more of weakness in the limbs. It was concluded that the questionnaire could be of great value in the before and after treatment situations and could be used to compare different treatment regimes. Thus, both of these studies used the same questionnaire (High Blood Pressure Health Survey) to measure the quality of life and side-effects of hypertensive patients undergoing drug-therapy. However, this questionnaire

addressed mainly the symptom domain of the quality of life spectrum. Ideally, the instrument of use should measure all three domains: function, perception, and symptom.

In addition, Bulpitt (1982) further investigated the effects of several other anti-hypertensive drugs on the quality of life. It was found that propranolol and bethanidine increased unsteadiness and weak limbs, and guanethidine produced unsteadiness, diarrhea, and failure of ejaculation. Depression and other psychiatric morbidity were also reported as a result of anti-hypertensive drug therapy in this study. In another survey conducted by Jachuck and colleagues (1982), the quality of life of 75 patients with controlled hypertension was assessed. The group consisted of 41 women and 34 men. The patients were given a self-administered questionnaire to register their progress. They were also asked to answer by direct questioning if they had felt improved, worse, or had found no appreciable difference in their clinical and general condition after therapy. A relative or close companion of each patient was also given a self-administered questionnaire (Quality of Life Impairment Scale-QLIS) and was requested to respond without consulting the

patient. The overall assessment of the general practitioner was also recorded. The responses from the doctors, patients, and the close companions were assessed separately by an observer who had no knowledge of the patients nor their sex or therapeutic regime. The QLIS asked the relative or close friend to evaluate adverse changes in the patient in 20 areas and yielded a score of 0 to 32. The scale included a sex interest item which was not scored since the respondent may not have been able to evaluate the patient's sexuality. The scores from the scale were divided into three groups representing mild, moderate, and severe changes in quality of life. The QLIS, as its name implied, only assessed the degree of impairment of life. Also, it mainly addressed questions related to the function domain of the quality of life spectrum. The results of the overall assessment of the doctors, the patients, and that of their close companions differed considerably. The doctors registered 100% improvement as (a) they had adequately controlled the blood pressure, (b) there had been no clinical deterioration since the treatment, and (c) the patients had not complained about the effect of treatment to the doctors. Further, 48% of the patients said they felt better as

a result of starting the treatment. In contrast, to the assessments of both physicians and the self-reporting of the patients, the relative's questionnaire rated 19 patients (25%) to have suffered mild adverse changes and 33 patients (30%) to have severe impairment after receiving anti-hypertensive therapy. The deteriorations were attributed to undue preoccupation with sickness, decline in energy, general activity, and sexual activity. The authors suggested the use of such an assessment in social readjustment and occupational rehabilitation.

Croog et al. (1986) investigated the effects of captopril, methyldopa, and propranolol on the quality of life of 626 men with mild to moderate hypertension. All patients were caucasian males between the ages of 21 and 65 years, full-time employed, and had a primary diagnosis of essential hypertension (a median diastolic blood pressure in the seated position of 92 to 109 mmHg on three determinations within five minutes). Upon entry into the study, each patient was randomly assigned to receive one of three drugs (captopril, methyldopa, or propranolol) in two different periods. Period A being the placebo period and period B being the

active medication period. Placebo tablets with the same physical characteristics as each of the test drugs were prepared. During period A, the patient took three placebo tablets twice a day for four weeks. During period B, the patients received the assigned active drug plus two placebo tablets twice a day to maintain the double blinding. The patients were medically evaluated at 2-week intervals during period A and on a monthly basis during period B. For the quality of life study, interviews were carried out in a four-stage program: stage I, at the beginning of period A; stage II, at the end of the four weeks in period A; stage III, after eight weeks of period B; and stage IV, after 24 weeks of period B. The quality of life assessment was based on five measures: (a) the sense of well-being and satisfaction with life, (b) the physical state, (c) the emotional state, (d) intellectual functioning, and (e) the ability to perform in social roles and the degree of satisfaction derived from those roles. The results indicated that the three treatment groups did not differ in terms of measures of socialization, visual memory, and some other aspects of cognitive functioning and emotional distress. However, clear differences in other

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indices of quality of life were evident. At 24 weeks, the captopril group was better off than the methyldopa in terms of the measures of well-being, anxiety, depression, physical symptoms, sexual dysfunction, cognitive function, work performance, and satisfaction with life. Patients taking propranolol also reported better work performance than patients taking methyldopa. The authors concluded that anti-hypertensive agents have different effects on the quality of life and can be meaningfully assessed with available psychosocial measures. However, the use of 10 different instruments to measure the quality of life may not be feasible to most clinical trials although all three domains of the quality of life spectrum in this study were addressed. The main restrictions included the need of a highly trained staff to administer the tests and time constraints.

In summary, the studies discussed above have shown that different anti-hypertensive drugs influence various aspects of the quality of life of patients. Also, the questionnaires used to assess the quality of life of patients did not always evaluate the three domains of the quality of life spectrum: function, perception, and symptom.

Ideally the instrument of use should include all three domains.

Labeling (Treatment Situation)

Increased absenteeism from work has been found in hypertensive patients who were aware of their disease status (Fletcher et al., 1985; Haynes, Sackett, Taylor, Gibson, & Johnson, 1978). Diagnosed hypertensive patients have been described to generally not feel as well as normotensive control subjects, and this feature appears unchanged by treatment. Hayne et al. (1978) investigated labeled hypertensive employee absenteeism at a Canadian steel mill. Data were gathered before and after screening steel workers for hypertension. In brief, two-thirds (5,400) of the male employees were asked whether they had ever been told that they had high blood pressure, after which they were screened for hypertension. A total of 245 males met the following criteria: average fifth-phase diastolic blood pressure (higher than 95 mmHg), no anti-hypertensive therapy for at least six months before the screening, no other daily medications, and no remedial secondary form of hypertension. Ninety-four percent of these males

consented to participate in a six-month randomized trial of compliance improving strategies.

Absenteeism was determined directly from routine company time-clock records. The results showed that labeling of patients as hypertensive increased the mean absenteeism 5.2 days per year ($SD \pm 2.3$ days). This eighty percent increase exceeded the rise in absenteeism in the general employee population during this period. The main factors associated with increased absenteeism were becoming aware of the condition and low compliance with treatment.

Subsequent absenteeism among patients unaware of their hypertension before screening was not related to the degree of hypertension, whether the worker was started on therapy, the degree of blood pressure control achieved, or exposure to attempts to promote compliance. It was concluded that these results have major implications for hypertension screening programs, especially since absenteeism rose among those previously unaware of their condition, regardless of whether anti-hypertensive therapy was begun.

In addition, several other studies have shown the effect of labeling on various measures of psychological functions and well-being. The Dofasco

study (Mossey, 1981) provided an opportunity to study prospective changes in psychosocial behavior as a result of labeling. Baseline data were collected on 230 steel workers with hypertension before their blood pressure status was revealed to them. The data included measures of marital adjustment and self-perceptions of well-being, aliveness, powerfulness, and goodness. Follow-up measurements of these attributes were gathered six and twelve months after screening. When the men with hypertension were compared with age-matched untreated normotensive controls, a deterioration in marital satisfaction was observed. This observed decrease in marital satisfaction occurred independent of prior knowledge of hypertension status, treatment status, or compliance and was related to an increase in absenteeism.

Two cross-sectional studies offer additional evidence that there is an impact from patient labeling when hypertension is diagnosed (Monk, 1981; Soghikian, Fallick, Hunter, & Vry, 1981). In a multi-phased health check-up program, 52,948 people underwent diastolic pressure checks, completed a self-administered questionnaire on whether they had been labeled, and answered questions that measured

their psychological status (Soghikian et al., 1981). Since only one blood pressure measurement was taken and in view of the variability associated with the one time reading, hypertension was defined as a diastolic pressure in excess of 105 mmHg. From the first two measures, four groups were formed:

- (a) labeled hypertensives, (b) unaware hypertensives, (c) mislabeled normotensives, and (d) normotensives.

Analysis were then carried out to summarize the psychological distress of each group, adjusted for age, gender, race, and treatment status. Labeled individuals (group 1 and 3) exhibited uniformly greater psychological distress than the other two groups. There was no difference in psychological distress between unaware hypertensives and normotensives. A striking finding of this study was the high level of psychological distress among people with normal blood pressure who had been mislabeled and were convinced they had hypertension. Finally, when blood pressure was taken into account, greater psychological distress was observed among the untreated individuals than among those who were successfully controlled.

A second cross-sectional study was completed in early 1970 as part of the first health and nutrition

survey conducted in the United States (Monk, 1981).

A representative sample of 3,854 individuals were interviewed, examined, and administered a questionnaire about their psychological well-being. Blood pressure status was not known at the time the general well-being questionnaire was administered. Blood pressure ratings in excess of 160/95 mmHg met the definition of hypertension, and people with hypertension were divided into three groups: (a) unaware, (b) labeled but untreated, and (c) labeled and treated. After adjustment for age, gender, and racial differences, a clear hierarchy of psychological well-being was found among unaware hypertensive patients and normotensives, who were identical. Labeled and treated hypertensive patients were at the other end of the hierarchy, with the lowest psychological well-being, and labeled but untreated hypertensive patients in the middle. Finally, labeled and treated hypertensive patients reported a significantly higher rate of emotional problems and nervous breakdowns than the unaware group.

In summary, diagnosed hypertensives have been described to generally feel less well than normotensive control subjects. Also, diagnosed

hypertensives have shown a decrease in marital satisfaction, greater psychological distress, and lower ratings of psychological well-being.

Summary

This chapter included a discussion of quality of life and hypertension, measurement of the quality of life, effect of long-term drug therapy on the quality of life, and labeling.

CHAPTER III

Methods

Introduction

In this chapter information on the subjects, the instrument, and measurements and methods is presented. The measurements and methods include content validity, reliability measurement, collection of data, and physiological parameters.

Subjects

Thirty-nine hypertensive male patients who underwent long-term drug therapy were used as subjects. The subjects ranged in age from 31-57 years. All subjects had mild to moderate essential hypertension (i.e., diastolic blood pressure ranging from 95 to 109 mmHg) measured on two occasions that were separated by two weeks. All subjects were involved in a 2-year study of anti-hypertensive effects of fosinopril sodium, propranolol hydrochloride, and a program of aerobic exercise. The study was concluded in June, 1989. All procedures

were fully explained to the subjects and consent was obtained from each subject prior to any data collection (Appendix A).

Instrument (Appendix B)

A quality of life questionnaire developed by the Institute for Aerobics Research (Dallas, TX) for hypertensive patients was examined for its reliability and content validity. The original questionnaire contained only 10 questions (questions 1 through 10). For the purpose of this study, 11 more questions were added (questions 11 through 21). The new questions were developed according to the quality of life spectrum definition. For instance, questions 3, 5, 9, 10, 11, 12, 13, and 16 were intended to represent the function domain. Questions 1, 4, 6, 7, 8, 14, 15, and 17 were intended to represent the perception domain. Questions 2, 18, 19, 20, and 21 were intended to represent the symptom domain.

Content Validity

Twenty experts evaluated the questionnaire for clarity and content validity. Experts were given a complete definition for the three domains (function, perception, and symptom) of the quality of life spectrum. Each expert, then, subjectively classified each question in the domain to which he/she believed each question belonged.

A principal components factor analysis with an orthoganal rotation was used. Eigenvalues greater than 1.0 were used as the criterion for identification of the significant constructs (factors) represented by the 21 questions in the questionnaire. Factors were given descriptive titles based on the questions determined to be most highly related to a factor loading. This classification was then compared and analyzed with the subjective evaluation of the experts as well as the original classification as identified in the previous section.

In order to determine the internal consistency (reliability) of the questionnaire, a coefficient alpha was calculated for the questions within each of the significant constructs (factors) identified by the factor analysis. An alpha coefficient greater than .70 was considered to be indicative of acceptable reliability.

Physiological Parameters

The physiological parameters of each patient were measured by the physicians involved in the long-term drug therapy study. Physiological parameters measured included supine systolic and diastolic blood pressure, resting heart rate, age, height, and weight.

Collection of Data

The hypertensive patient's quality of life questionnaire was given once to all patient's. The questionnaire was handed to each patient during his blood pressure check visit at the Cooper clinic in

May, 1989. They were asked not to write their names on the questionnaire. A code number (1-39) was assigned to each patient upon receiving the questionnaire. The number was written by the researcher, Carla Sottovia, in the upper right hand corner of the questionnaire's cover page. Further, each code number was matched to each patient's initials. All patients received a copy of their assigned code number and they could withdraw their participation in the study at any time. Finally, all questionnaires and code numbers were kept in a confidential file by the researcher during the study and after the completion of the study. All patients were scheduled for their blood pressure check during the weeks of (May 15th thru May 19th and May 22th thru May 25th). Approximately 10 patients were checked a day. Patients were scheduled at one hour intervals and were asked to complete the questionnaire before their blood pressure measurement.

Summary

This chapter included information on subjects for the study, the instrument, and measurements and

methods. The measurements and methods included content validity, estimation of reliability, collection of data, and physiological parameters.

CHAPTER IV

Results, Discussion and Conclusions

Introduction

This chapter includes analysis of data, summary of findings, discussion of findings, conclusions, weaknesses of study, and recommendations for future research. The analysis of data includes the physiological parameters of subjects, descriptive statistics of questions, descriptive responses of subjects, and estimation of content validity and reliability measurements.

Analysis of Data

Physiological Parameters of Subjects: Table 1 and Table 2.

Thirty-nine hypertensive patients were used as subjects. Their ages ranged from 31 to 57 years ($M \pm SD = 44.7 \pm 5.5$ years). Diastolic blood pressure ranged from 64 to 108 mmHg ($M \pm SD = 85.6 \pm 7.6$ mmHg) and systolic blood pressure ranged from 112 to 184 mmHg ($M \pm SD = 135.2 \pm 16.8$ mmHg).

Table 1

Physiological Parameters of Subjects

<u>Sub.</u>	<u>Sup.B.P.</u>	<u>R.H.R.</u>	<u>Age</u>	<u>Hgt</u>	<u>Wt</u>
1	122/86	47bpm	48 yrs	180 cm	78 kg
2	112/64	54 bpm	36 yrs	175 cm	111 kg
3	124/82	60 bpm	39 yrs	179 cm	94 kg
4	168/94	58 bpm	47 yrs	158 cm	69 kg
5	140/92	48 bpm	47 yrs	182 cm	106 kg
6	112/82	68 bpm	44 yrs	195 cm	80 kg
7	184/108	63 bpm	48 yrs	169 cm	96 kg
8	114/82	54 bpm	45 yrs	169 cm	100 kg
9	132/96	75 bpm	31 yrs	191 cm	93 kg
10	132/82	74 bpm	43 yrs	187 cm	100 kg
11	116/78	54 bpm	43 yrs	173 cm	95 kg
12	138/88	60 bpm	37 yrs	182 cm	93 kg
13	169/92	60 bpm	47 yrs	181 cm	70 kg
14	128/76	54 bpm	42 yrs	191 cm	110 kg
15	130/86	47 bpm	53 yrs	184 cm	102 kg
16	128/88	65 bpm	51 yrs	166 cm	97 kg
17	140/74	47 bpm	48 yrs	176 cm	77 kg
18	138/82	50 bpm	48 yrs	182 cm	88 kg

Table 1 (Continued)

Physiological Parameters of Subjects

<u>Sub.</u>	<u>Sup.B.P.</u>	<u>R.H.R.</u>	<u>Age</u>	<u>Hgt</u>	<u>Wt</u>
19	138/86	57 bpm	52 yrs	170 cm	72 kg
20	132/86	60 bpm	33 yrs	170 cm	68 kg
21	126/80	44 bpm	44 yrs	172 cm	77 kg
22	128/84	52 bpm	46 yrs	172 cm	72 kg
23	124/76	57 bpm	44 yrs	189 cm	118 kg
24	144/82	57 bpm	44 yrs	173 cm	65 kg
25	130/86	54 bpm	36 yrs	175 cm	102 kg
26	148/90	75 bpm	57 yrs	180 cm	75 kg
27	128/96	58 bpm	43 yrs	175 cm	83 kg
28	136/88	68 bpm	45 yrs	172 cm	101 kg
29	120/92	68 bpm	46 yrs	181 cm	125 kg
30	122/86	75 bpm	53 yrs	176 cm	97 kg
31	172/90	89 bpm	39 yrs	190 cm	85 kg
33	132/76	67 bpm	47 yrs	175 cm	90 kg
34	124/88	48 bpm	52 yrs	176 cm	90 kg
35	120/88	48 bpm	45 yrs	177 cm	83 kg
36	162/98	73 bpm	47 yrs	177 cm	85 kg
37	132/86	59 bpm	41 yrs	176 cm	90 kg
38	156/80	60 bpm	42 yrs	177 cm	85 kg
39	144/80	58 bpm	40 yrs	180 cm	80 kg

Table 2

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Descriptive Statistics of the Physiological
Parameters of Subjects

	Mean	Standard Deviation
Systolic Blood Pressure:	135.2 mmHg	16.8 mmHg
Diastolic Blood Pressure:	85.6 mmHg	7.6 mmHg
Resting Heart Rate:	59.7 bpm	9.8 bpm
Age:	44.7 yrs	5.5 yrs
Height:	177.5 cm	7.5 cm
Weight:	89.5 kg	13.9 kg

Also, the subjects' height and weight ranged from 158 cm to 191 cm ($M \pm SD = 177.5 \pm 7.5$ cm) and 65 kg to 125 kg ($M \pm SD = 89.5 \pm 13.9$ kg), respectively. Finally, resting heart rate ranged from 47 bpm to 89 bpm ($M \pm SD = 59.7 \pm 9.8$ bpm).

Descriptive Statistics of questions: Table 3.

This table presents the means and standard deviations of the response of the patients to the questions. The mean and standard deviations for the questions ranged from 1.36 to 2.56 and .62 to 1.21, respectively.

Descriptive responses of subjects: Table 4.

This table describes the frequency of responses of all questions. The percentage of responses of all questions occurred most frequently on question choices 1 through 3 (positive responses), with question choice 2 having the highest percentage of responses.

Content Validity: Table 5.

Twenty experts evaluated the quality of life questionnaire for its content validity. Each expert classified each question according to the quality of life domain in which he/she believed each question belonged. A complete definition of the three domains of the quality of life spectrum (function,

Table 3
Descriptive Statistics for the 21 Questions

<u>Question</u>	<u>Mean</u>	<u>Standard Deviation</u>
1	2.28	1.00
2	2.56	.99
3	2.41	1.07
4	1.90	.88
5	1.64	.71
6	2.36	1.20
7	1.67	.62
8	2.00	.86
9	2.31	.89
10	1.95	1.21
11	1.36	.63
12	2.00	.79
13	2.13	.86
14	2.56	1.10
15	1.67	.66
16	1.97	.71
17	1.97	.71
18	1.85	.71
19	2.31	.86
20	1.44	.60
21	1.77	.67

Table 4

Descriptive Responses of Subjects

<u>Question Choices (1-6)/ Percentage of Responses</u>						
Questions	Response 1: Very Positive			Response 6: Very Negative		
	1	2	3	4	5	6
	<hr/>					
1	28.2%	25.6%	35.9%	10.3%		
2	7.7%	51.3%	23.1%	12.8%	5.1%	
3	15.4%	48.7%	23.1%	5.1%	7.7%	
4	35.9%	43.6%	17.9%		2.6%	
5	48.7%	38.5%	12.8%			
6	20.5%	48.7%	17.9%		12.8%	
7	41.0%	51.3%	7.7%			
8	30.8%	43.6%	20.5%	5.1%		
9	17.9%	43.6%	28.2%	10.3%		
10	41.0%	43.6%	5.1%	2.6%	5.1%	2.6%
11	71.8%	20.5%	7.7%			
12	28.2%	46.2%	23.1%	2.6%		
13	23.1%	48.7%	20.5%	7.7%		
14	17.9%	30.8%	33.3%	12.8%	5.1%	
15	43.6%	46.2%	10.3%			

Table 4 (Continued)

Descriptive Responses of SubjectsQuestion Choices (1-6)/ Percentage of Responses

Questions	Response 1: Very Positive		Response 6: Very Negative			
	1	2	3	4	5	6
16	25.6%	51.3%	23.1%			
17	25.6%	51.3%	23.1%			
18	33.3%	48.7%	17.9%			
19	20.5%	33.3%	41.0%	5.1%		
20	61.5%	33.3%	5.1%			
21	35.9%	51.3%	12.8%			

Table 5

Content Validity

Number of Observations per Domain for Each Question (20 observations maximum)					
Questions	Domain Classified	Agreement			
		Between Experts	Perc. Symp. Func.		
1	Perception	90%	18	0	2
2	Symptom	75%	4	15	1
3	Function	100%	0	0	20
4	Perception	100%	20	0	0
5	Function	90%	1	1	18
6	Perception	55%	11	0	9
7	Perception	60%	12	0	8
8	Perception	95%	19	1	0
9	Function	60%	8	0	12
10	Function	55%	9	0	11
11	Function	95%	0	1	19
12	Function	80%	4	0	16

Table 5 (Continued)

Content Validity

Number of Observations per Domain for Each Question (20 observations maximum)					
Questions Classified	Domain	Agreement Between Experts	Perc. Symp. Func.		
13	Function	70%	5	1	14
14	Perception	60%	12	1	7
15	Perception	80%	16	1	4
16	Function	85%	2	1	17
17	Perception	80%	16	1	4
18	Symptom	95%	0	19	1
19	Symptom	95%	1	19	0
20	Symptom	95%	0	19	1
21	Symptom	95%	0	19	1

perception, and symptom) was given beforehand to each expert. This subjective evaluation showed the following responses:

1) Twenty experts agreed with each other that questions 18, 19, 20, and 21 (100% agreement) were measuring the symptom domain. Also, fifteen experts classified question 2 in this domain (75% agreement).

2) Twenty experts agreed with each other that question 4 was measuring the perception domain (100% agreement). Further, 19 and 18 experts classified questions 8 and 1 in this domain, respectively (95% and 90% agreement). Moreover, 16 experts classified questions 15 and 17 in this domain (80% agreement) as well. In addition, 12 experts classified questions 7 and 14 in this domain (60% agreement). Finally, 11 experts agreed that question 6 was measuring the perception domain (55% agreement).

3) Question 3 was classified in the function domain with 100% agreement among the experts. Also, questions 11, 5, 16, 12, and 13 showed a 95%, 90%, 85%, 80%, and 70% agreement in classification, respectively, among the experts. Thus, these questions were classified in the function domain as well. In addition, questions 9 and 10 showed a 60% and 55% agreement, respectively.

In summary, 10 questions (1, 3, 4, 5, 8, 11, 18, 19, 20, and 21) were classified in the same domain as originally proposed in chapter three with 90% or higher agreement among the experts. On the other hand, questions 2, 6, 7, 9, 10, 12, 13, 14, 15, 16, and 17 demonstrated less than 90% agreement among the experts. Also, these questions were not modified nor eliminated for the factor analysis .

Content Validity: Factor Analysis (Table 6).

The results of the factor analysis procedures identified five significant factors on the basis of the eigenvalues-greater-than-one rule. Questions 1, 8, 9, 15, 16, 17, 18, and 21 were most highly loaded on factor I (Perception domain) with factor loadings of .72, .74, .67, .77, .87, .87, .54, and .63, respectively. Further, questions 3, 5, 6, 10, and 13 were most highly loaded on factor II (Function domain) with factor loadings of .60, .70, .83, .72, and .65, respectively. Questions 2, 7, 19, and 20 were most highly loaded on factor III (Symptom domain) with factor loadings of .58, .60, .80, and .57, respectively. In addition, questions 11 and 12 were most highly loaded on factor IV (Daily Routine

Table 6

Factor Matrix for the 21 Questions (Variables)

		<u>Factors: I II III IV V</u>				
<u>Item</u>	<u>Items</u>					
<u>Content</u>						
Perception	1	<u>.72</u>	.13	.26	.28	.15
Domain	8	<u>.74</u>	.19	.17	.43	.16
	9	<u>.67</u>	.07	.50	.04	.37
	15	<u>.77</u>	.26	.04	.30	.03
	16	<u>.87</u>	-.02	.30	-.08	.11
	17	<u>.87</u>	-.02	.30	-.08	.11
	18	<u>.54</u>	.43	.51	.16	.02
	21	<u>.63</u>	.26	.08	.36	-.05
Function	3	.57	<u>.60</u>	-.03	-.21	.05
Domain	5	.21	<u>.70</u>	.09	.33	-.13
	6	.05	<u>.83</u>	.16	-.14	.04
	10	-.10	<u>.72</u>	.06	.15	.48
	13	.21	<u>.65</u>	-.02	.43	.37

Table 6 (Continued)

Factor Matrix for the 21 Questions (Variables)

		<u>Factors: I II III IV V</u>				
Item	Items					
<u>Content</u>						
Symptom	2	.15	-.01	<u>.58</u>	.05	.14
Domain	7	.49	.01	<u>.60</u>	.26	.09
	19	.16	.24	<u>.80</u>	.08	.06
	20	.24	-.01	<u>.57</u>	.44	-.46
<hr/>						
Daily Routine						
and						
Intellectual	11	.07	-.01	.35	<u>.83</u>	.15
Functions	12	.40	-.40	-.03	<u>.56</u>	.25
<hr/>						
Life						
Satisfaction						
and Sense of	4	.47	.36	.24	.12	<u>.57</u>
Well-Being	14	.24	.07	.20	.16	<u>.85</u>

and Intellectual Function domain) with factor loadings of .83 and .56, respectively. Finally, questions 4 and 14 most highly loaded on factor V (Life Satisfaction and Sense of Well-Being domain) with factor loadings of .57 and .85, respectively.

Reliability Measurement: Coefficient Alpha.

Coefficient alpha was used to determine the internal consistency of the questions within each identified factor. An alpha coefficient greater than .70 was considered to be indicative of acceptable reliability. Factor I had an alpha coefficient of .93. Factor II, III, IV, and V had alpha coefficients of .81, .68, .63, and .76, respectively.

Summary of Findings

The results of the factor analysis (content validity measurement) identified five distinct factors rather than three as originally suggested. The five constructs were named as follow: perception domain (factor I), function domain (factor II), symptom domain (factor III), daily routine and intellectual functions (factor IV), and life satisfaction and sense of well-being (factor V). Further, the results of the factor analysis also

showed a positive agreement with the original classification as well as the experts for questions 1, 8, 15, 17 (factor I), 3, 5, 10, 13 (factor II), and 2, 19, 20 (factor III), but not for questions 4, 6, 7, 9, 11, 12, 14, 16, 18, and 21. Several questions, should be rewritten to eliminate ambiguity and then be retested for content validity using factor analysis. The following questions should be rewritten: 6, 7, 9, 16, and 18. Overall, this questionnaire demonstrated poor content validity.

Factors I, II, and V had high internal consistency as evidenced by alpha coefficients of .93, .81, and .76, respectively. On the other hand, factors III and IV had low alpha coefficients (.68 and .63, respectively) and hence, moderate reliability. This was perhaps due to the ambiguity of some questions and possibly a close relationship between the function and symptom domains.

Discussion of Findings

Factor Analysis

Factor I showed a fair agreement with the original and subjective evaluation of the questionnaire. Questions 1 and 3 had high agreement among the experts (90%) as well as factor loadings of .72 and .74, respectively. Questions 15 and 17 demonstrated less than 90% agreement among the experts. Further, these questions appeared to be related to perception of feelings, such as a sense of health status and well-being. On the other hand, questions 9 and 16 which were originally classified in the function domain, had fairly high loadings (.67 and .87, respectively) on factor I (perception domain). It appeared that both questions could in reality have been classified under two domains (function and perception). According to the definition (Wenger et al., 1984a), perceptions are defined as an individual's view of his or her situation. Of particular interest are perceptions of general health status, level of well-being, and satisfaction with life. In contrast, functions include activities involved in daily personal functioning such as

dresssing, eating, meeting basic individual needs, and maintaining adequate physical activity. Thus, question 9 (How much energy or vitality do you have? In particular with reference to your exercise program or participation in physical activities.) could have been interpreted as a perception of general health status (i.e., How much energy do you perceive you have?) and/or the ability to perform physical activities (function domain). Similarly, question 16 (How much energy do you have in order to participate in your community activities?) could have also been interpreted as a perception of general health status (i.e., How much energy do you perceive you have to participate in your activities?) and/or the ability to participate in social activites (function domain). Perhaps, if worded differently, these questions could have been classified clearly under one particular domain. Further, question 18 and 21 were originally classified in the symptom domain with a 95% agreement among the experts. However, question 18 (How often do you feel weak, tired, or fatigue to perform your job?) could have possibly been interpreted as one's perception of health status rather than just physical symptoms.

In summary, factor I appeared to represent the perception domain of the quality of life spectrum.

Factor II (function domain) demonstrated a fair agreement with the original and subjective evaluation of the questionnaire. All questions (3, 5, 10, and 13) with the exception of question 6 (How satisfied are you with your sex life?) were originally classified under the function domain. These questions were related mostly to one's functional capacity within one's job, personal relationship, community, and social activities. Question 6, however, could have possibly been interpreted in either domain: perception of feelings (How do you perceive your sex life?) and/or function domain (Are you satisfied with your ability to perform sex?).

Factor III (symptom domain) had questions which were originally classified under the symptom domain with the exception of question 7. This question, (Do you feel healthy enough to participate in your usual activites?) could have been interpreted in probably all three domains. For example, it could have been interpreted under the function domain (Can you participate in your usual activities?). Further, this same question could have been interpreted under the perception domain (Do you perceive yourself

healthy?). Finally, it could have been interpreted under the symptom domain (Do you feel any physical symptoms?).

Factor IV contained questions related to one's ability of performing daily personal tasks and the ability to cope with stress (questions 11 and 12, respectively). Further, these questions were originally classified in the function domain with a 95% and 80% agreement among the experts for questions 11 and 12, respectively. However, it may be plausible to rewrite questions 11 and 12 so they would fit under the function domain. For instance, question 11 could be rewritten as follows: At home, how often can you perform your usual activities? (i.e., rising, dressing, feeding yourself, maintaining adequate physical activity). Also, question 12 could be rewritten as follows: (At work, how often do stressful situations interfere with your job performance?). This factor was named as daily routine and intellectual functions.

Factor V contained questions (4 and 14) related to the degree of satisfaction of one's personal life and the degree of one's interest at work which were originally classified in the perception domain with a 100% and 60% agreement among the experts,

respectively. Also, it may be reasonable to rewrite questions 4 and 14 so they would fit under the perception domain. For example, question 4 could be rewritten as follows: (Are you satisfied with your life in general?). Also, question 14 could be rewritten as follows: (At work, how often do you feel satisfied with your job?). This factor was named as life satisfaction and a sense of well-being.

In summary, the results of the factor analysis (content validity measurement) identified five distinct constructs rather than three as originally proposed. Thus, the five constructs were named as follows: perception domain (factor I), function domain (factor II), symptom domain (factor III), daily routine and intellectual functions (factor IV), and life satisfaction and sense of well-being (factor V). Further, questions 1 and 8 (factor I); 3 and 5 (factor II); and 19 and 20 (factor III) demonstrated 90% or higher agreement with the original classification as well as the experts classification. It was suggested that questions 4, 6, 7, 9, 11, 12, 14, 16, and 18 should be rewritten and retested for content validity. Finally, it was concluded that this questionnaire demonstrated poor content validity.

Reliability measurement

A coefficient alpha was used to determine the internal consistency of all questions within each identified factor. Factor I showed an alpha coefficient of .93. Factor II and V showed alpha coefficients of .81 and .76, respectively. However, factors III and IV had alpha coefficients of .68 and .63, respectively. These values were considered lower than the acceptable value of R greater than .70.

The author believed that the main reason for such low alpha coefficients for factors III and IV were due perhaps to the ambiguity of some questions as discussed above and possibly a close relationship between the function and symptom domains. In summary, factor I, II, and V had high alpha coefficients for the reliability measurement which included questions related to one's perception of feelings (factor I), functional capacity (factor II), and life satisfaction and sense of well-being (factor V). On the other hand, factors III (symptom domain) and IV (Daily Routine and Intellectual functions) did not have high alpha coefficients.

Conclusions

Within the limits of this study the following conclusions were made:

(1) The results of the factor analysis (content validity measurement) identified five distinct constructs rather than three as originally proposed. The five constructs were the following: perception domain (factor I), function domain (factor II), symptom domain (factor III), daily routine and intellectual functions (factor IV), and life satisfaction and sense of well-being (factor V).

(2) The results of the factor analysis (content validity measurement) supported the original classification as well as the experts' classification with a 90% agreement for questions 1 and 8 (factor I), 3 and 5 (factor II), and 19 and 20 (factor III); but not for questions 4, 6, 7, 9, 11, 12, 13, 14, 16, and 18. It was concluded that this questionnaire demonstrated poor content validity.

(3) Factors I, II, and V had high internal consistency as evidenced by alpha coefficients of .93, .81, and .76, respectively. On the other hand, factors III and IV had low alpha coefficients (.68 and .63, respectively) and hence reliability, due

perhaps to the ambiguity of some questions and possibly a close relationship between the function and symptom domains.

Weaknesses of Study

The ambiguity of several questions may have affected the results of the factor analysis used to determine content validity and consequently, the reliability of the Quality of Life Questionnaire.

Recommendations for Future Research

Within the limits of this study the following recommendations were made:

(1) Future research should rewrite questions 4, 6, 7, 9, 11, 12, 14, 16 and 18, and thus retest the questionnaire for content validity.

(2) Future research should use a larger sample of subjects than the sample size used in this study.

(3) Future research with a larger sample size may use a Discriminant Analysis to determine which questions best discriminate between the quality of life factors.

Summary of Chapter

This chapter presented the introduction, analysis of data, summary of findings, discussion of findings, conclusions, weaknesses, and recommendations for future research.

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APPENDIX A

STUDY TO ESTIMATE THE RELIABILITY OF A QUALITY OF LIFE QUESTIONNAIRE DESIGNED FOR HYPERTENSIVE PATIENTS

Invitation to Participate

You are invited to participate in a study investigating the reliability of a quality of life questionnaire designed for hypertensive patients undergoing long-term drug therapy. This study will be conducted in the Cooper Clinic Laboratory, in Dallas, TX.

Purpose of the Study

The purpose of this study is to estimate the reliability of a quality of life questionnaire for hypertensive patients undergoing long-term drug therapy.

Explanation of Procedures

Questionnaire Completion

The hypertensive patient's quality of life questionnaire will be given once to all patients in order to test its reliability. Each patient will

complete one copy of the questionnaire during their blood pressure check visit at the Cooper Clinic. Also, the patient will be asked not to write their name on the questionnaire. Once completed, all answers will be kept in confidence to ensure proper statistical measurements.

Benefits for Participation in the Study

You will benefit from this study by enhancing the communication between you and your doctor, which in turn will lead to better health care. By knowing how your present medication is affecting your quality of life, proper changes can be made in your treatment, which will best meet your needs. This questionnaire will also help many other patients (present and future) that are, or will be undergoing long-term drug therapy for hypertension, as well as help the doctors.

Assurance of Confidentiality

The results of this study may be used for research publication and presentation. Your right to confidentiality will be protected unless your expressed consent is granted prior to the publication and presentation of the data.

Withdrawal from the Study

You may withdraw your consent and discontinue your participation in this study at any time. You may also decline to answer any questions or items on the quality of life questionnaire.

The questionnaire will be handled by Carla Sottovia. If you have any questions about the study, please feel free to ask. If additional questions come up later, call Carla at (214) 960-8557. For questions, comments, or complaints about research subject's rights, contact Dr. Serena Standford, Associate Academic Vice President of Graduate Studies and Research, at (408) 924-2480.

Consent

By signing this form, you are agreeing:

- (1) You decided to participate in this study having read the information provided above.
- (2) You understand you can withdraw at any time.
- (3) You understand that your name will be kept confidential except with your expressed consent.

Signature _____ Date _____

Print Name _____

Signature of Witness _____

Signature of Investigator _____

APPENDIX B

HYPERTENSIVE PATIENT'S QUALITY OF LIFE QUESTIONNAIRE

The enclosed brief questionnaire is designed to be answered by patients on blood pressure medication. The purpose of this questionnaire is to help increase communication between you and your doctor. Better communication leads to better health care.

Please answer the questions as best you can. Your answers will be treated in the strictest confidence.

Thank you very much.

Please answer the following questions by checking only one box for each question. Check the statement that comes nearest to what has been true for you during the last four weeks.

1) How are you feeling, in general?

1. In excellent spirits ()
2. In very good spirits ()
3. In good spirits, mostly ()

4. I'm up and down in spirits ()
5. In low spirits, mostly ()
6. In very low spirits ()

2) How often are you bothered by illness, aches, or pains?

1. None of the time ()
2. Rarely ()
3. Occasionally ()
4. About half the time ()
5. Almost everyday ()
6. Everyday ()

3) How active are you within the community, and with relatives and friends?

1. Very active ()
2. Usually active ()
3. Occasionally active ()
4. Somewhat less active lately ()
5. Rarely active lately ()
6. Not active at all time ()

4) How satisfied are you with your personal life?

1. Very satisfied ()
2. Usually satisfied ()
3. Occasionally satisfied ()
4. Rarely satisfied ()
5. Dissatisfied ()
6. Very dissatisfied ()

5) At work, how often do you have trouble performing your job?

1. None of the time ()
2. A little of the time ()
3. Some of the time ()
4. A good bit of the time ()
5. Most of the time ()
6. All of the time ()

6) How satisfied are you with your sex life?

1. Very satisfied ()
2. Usually satisfied ()
3. Occasionally satisfied ()
4. Rarely satisfied ()
5. Dissatisfied ()
6. Very dissatisfied ()

- 7) Do you feel healthy enough to participate in your usual activities?
1. Yes, I feel healthy enough all the time
()
 2. Yes, I feel healthy enough most the time ()
 3. Occasionally, I don't feel healthy enough ()
 4. No, I rarely feel healthy enough ()
 5. Sometimes, I need help to participate in my usual activities ()
 6. Most of the time I need help to participate in my usual activities ()
- 8) How often do you feel depressed, down, or unhappy?
1. None of the time ()
 2. A little of the time ()
 3. Some of the time ()
 4. A good bit of the time ()
 5. Most of the time ()
 6. All of the time ()
- 9) How much energy or vitality do you have?
(In particular with reference to your

exercise training program or participation in physical activities.)

1. Very energetic ()
2. Fairly energetic most of the time ()
3. My energy level varies quite a bit ()
4. Generally low in energy ()
5. Very low in energy most of the time ()
6. No energy at all; I feel tired, worn out ()

10) How satisfied are you in your relationships with your spouse and family?

1. Very satisfied ()
2. Usually satisfied ()
3. Occasionally satisfied ()
4. Rarely satisfied ()
5. Dissatisfied ()
6. Very dissatisfied ()

11) At home, how often do you have trouble in performing your usual activities? (i.e., rising, dressing, feeding yourself, or maintaining adequate physical activity).

1. None of the time ()
2. A little of the time ()

- 3. Some of the time ()
- 4. A good bit of the time ()
- 5. Most of the time ()
- 6. All of the time ()

12) At work, how often do you have trouble coping with stressful situations?

- 1. None of the time ()
- 2. Rarely ()
- 3. Occasionally ()
- 4. About half the time ()
- 5. Almost everyday ()
- 6. Everyday ()

13) How often does stress interfere in your relationship with your spouse and family?

- 1. None of the time ()
- 2. A little of the time ()
- 3. Some of the time ()
- 4. A good bit of the time ()
- 5. Most of the time ()
- 6. All of the time ()

14) At work, how often do you feel withdrawn, uninterested with your job?

1. None of the time ()
2. Rarely ()
3. Occasionally ()
4. About half the time ()
5. Almost everyday ()
6. Everyday ()

15) How satisfied are you in your relationship with your friends?

1. Very satisfied ()
2. Usually satisfied ()
3. Occasionally satisfied ()
4. Rarely satisfied ()
5. Dissatisfied ()
6. Very dissatisfied ()

16) How much energy do you have in order to participate in your community activities?

1. Very energetic ()
2. Fairly energetic most the time ()
3. My energy level varies quite a bit ()
4. Generally low in energy ()
5. Very low in energy most of the time ()
6. No energy at all ()

- 17) At work, how satisfied are you in your relationship with your co-workers?
1. Very satisfied ()
 2. Usually satisfied ()
 3. Occasionally satisfied ()
 4. Rarely satisfied ()
 5. Dissatisfied ()
 6. Very dissatisfied ()
- 18) How often do you feel weak, tired, or fatigued to perform your job?
1. None of the time ()
 2. A little of the time ()
 3. Some of the time ()
 4. A good bit of the time ()
 5. Most of the time ()
 6. Everyday ()
- 19) How often do you feel weak or exhausted to perform your regular exercise program?
1. None of the time ()
 2. Rarely ()
 3. Occasionally ()
 4. About half of the time ()
 5. Almost everyday ()

6. Everyday ()

20) How often do you feel physically sick to participate in your normal community activities?

1. None of the time ()
2. A little of the time ()
3. Some of the time ()
4. A good bit of the time ()
5. Most of the time ()
6. All of the time ()

21) How often do you have trouble falling to sleep (Insomnia)?

1. None of the time ()
2. Rarely ()
3. Occasionally ()
4. About half the time ()
5. Almost everyday ()
6. Everyday ()