# Applying Quality of Life Data in Practice

# **Considerations for Antihypertensive Therapy**

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Quality of life issues have become increasingly important in tailoring antihypertensive therapy to individual patients. The application of quality of life data to the practice setting is frequently difficult, however. The effective use of this information requires an understanding of its definition and measurement, as well as of study methods. Quality of life findings may be specific to particular disease states, patient populations, and pharmacologic agents. The addition of hydrochlorothiazide to concurrent methyldopa, propranolol, or captopril therapy has been reported to reduce patients' overall sense of well-being. β-Adrenergic blockers may exert either positive or negative effects on quality of life. Angiotensin-converting enzyme (ACE) inhibitors may have positive effects on quality of life; however, the cost of therapy is an important consideration. Information on calcium antagonists is limited. The findings of the Treatment of Mild Hypertension Study (TOMHS) may eventually provide comparative quality of life data on the four first-line antihypertensive therapies.

 ${f T}$  he 1988 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure has recommended four classes of antihypertensive drugs as initial therapy¹: diuretics,  $\beta$ -adrenergic blockers, angiotensin-converting enzyme (ACE) inhibitors, and calcium antagonists. The selection of an antihypertensive agent is frequently based on its overall side effect profile, as patients are often symptomatic only from their medications. Croog et al² first identified that antihypertensive agents may differ in their specific quality of life effects. These differences may have important implications for the long-term management of hypertension. The purpose of this paper is to review the considerations in applying quality of life data to the management of mild to moderate hypertension.

# **DEFINITION**

Quality of life may be described, very simply, as an individual's perceived ability to function normally within so-

Submitted, revised, November 29, 1988.

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ciety.<sup>3</sup> This concept may be defined more precisely in terms of the patient's functional capacity, perceptions, and symptoms.<sup>4</sup> The first component of functional capacity includes the physical aspects of the individual's life such as mobility and independence. Alterations in physical health may be identified by changes in behavior or performance.<sup>5</sup>

Social functioning encompasses both formal and informal activities with family, friends, and the community in general. These activities may occur in many settings, including especially the workplace.<sup>4</sup> Social functioning is assessed by the amount of interaction, as well as the degree of satisfaction or dissatisfaction, that typically results.<sup>5</sup>

Cognitive functioning covers such global areas as abstract reasoning, memory, judgment, and alertness. Emotional functioning assesses mood changes and sick role behaviors. The frequency and intensity of psychological distress, as well as the presence or absence of behavioral dysfunction, are evaluated.<sup>5</sup> Economic status is the final component of functional capacity and is that which provides adequately for life.

Patient perceptions regarding overall health status are included in quality of life assessments because the measures of functional capacity do not always cover this area. In addition, measures of behavioral dysfunction are inherently negative and do not include positive well-being and life satisfaction, which are central to the concept of quality of life.<sup>5</sup>

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#### **MEASUREMENT**

A "gold" standard for the measurement of quality of life does not yet exist. Questionnaires, completed either by the individual or a trained observer, form the basis of most quality of life assessments in clinical trials. A visual analogue or Likert scale is frequently utilized. The latter employs a scoring system with 5 to 7 descriptors such as "all of the time" or "none of the time." As reported by Guyatt,6 a Likert scale is easily understood by patients of varying educational backgrounds and requires only minimal instruction. In addition, the responses obtained may be more relevant to the physician in identifying small, yet clinically important, differences between two medications.6 A detailed critique of the existing instruments is beyond the scope of this paper; readers are referred to a recent review. Before using a specific assessment tool in practice, though, the instrument's validity, reliability, and sensitivity must be considered.

Validity is defined as the ability of an instrument to measure what it purports to measure. There are three types of validation: content, concurrent, and construct. Content validity focuses on the representativeness of the questions to what is being measured. Questionnaires must include items on functional capacity, patient perceptions of well-being, and overall symptoms to satisfy content validity in quality of life trials.

Concurrent validity compares instrument scores with one or more external criteria recognized to measure the attribute under study. Until a gold standard for quality of life studies is available, the concurrent validity of the existing instruments cannot be determined.

In the absence of valid external criteria, the predicted relationships between the new instrument and other measures are compared and referred to as construct validity. As an example, higher activity or functioning scores should be correlated with reduced complaint rates or lower psychiatric morbidity. 8

Reliability is a measure of the consistency of the information obtained by test and retest when the experimental condition or treatment remains constant. If an instrument is reliable, any observed differences may be attributed to changes in therapy.

The improvements or decrements in quality of life produced by antihypertensive therapy are frequently subtle. Instruments must be sensitive to these small, yet clinically important, changes. Sensitivity concerns remain a major limitation of the available tools.

# **EVALUATION OF CLINICAL STUDIES**

Croog et al<sup>2</sup> was the first to compare the quality of life effects of different antihypertensive medications. Their

study was also designed to test selected standard psychological measures to detect the influence of medications on quality of life measures. Six hundred twenty-six white, fully employed men between the ages of 21 and 65 years with mild to moderate hypertension were enrolled. Patients were randomly assigned to receive 80 mg of propranolol or 500 mg of methyldopa or 50 mg of captopril twice daily. Hydrochlorothiazide in dosages of 25 mg given twice daily was added to each regimen as needed for optimal blood pressure control. Quality of life interviews were conducted at the beginning and at the end of the placebo period as well as after 8 and 24 weeks of active drug therapy.

This study was the first to demonstrate that quality of life may be measured with the available psychosocial instruments and that there may be differences between antihypertensive medications. In evaluating this, as well as other quality of life studies, there are important considerations in applying the findings to practice.

#### **Disease State**

Quality of life for the asymptomatic ambulatory individual with mild hypertension should be expected to differ, for example, from that of the acutely ill, hospitalized patient with a life-threatening myocardial infarction. While  $\beta$ -adrenergic blockers may adversely affect quality of life in patients with mild hypertension, their use in the setting of a myocardial infarction may result in improvement in some areas of functioning. <sup>10</sup> The results of Croog et al<sup>2</sup> should not be extrapolated to the use of propranolol, as well as methyldopa and captopril, in other disease states.

#### **Patient Population**

The application of quality of life findings to the practice setting should also take into account differences in the patient population such as age and sex. Older patients, owing to their increased risk of side effects and to economic considerations, frequently represent a challenge to the physician. The findings of Croog et al<sup>2</sup> cannot be extrapolated to the geriatric patient with isolated systolic hypertension, since individuals over 65 years of age were specifically excluded.

The sex of a patient also may influence the applicability of quality of life results. 11,12 As reported by Bulpitt and Fletcher, 11 over 30 percent of female patients believed that hypertension or its treatment had adversely affected their lives. In the study by Croog et al<sup>2</sup> only male hypertensive patients were enrolled. It is currently unknown whether similar findings would be observed in women.

#### **Family Involvement**

The potential contribution of relatives in identifying subtle quality of life changes has been demonstrated by Jachuck et al<sup>13</sup> in a study of 75 patients receiving  $\beta$ -adrenergic blockers, methyldopa, or diuretics. Quality of life questionnaires assessing the overall effects of antihypertensive therapy on the patient were distributed to the individuals. their relatives, and their primary physicians. Based on the adequacy of blood pressure control and the absence of specific complaints, 100 percent of the physicians reported improvement, while only 48 percent of patients responded similarly. Ninety-eight percent of relatives, however, considered the patient to have a mild or moderate or severe impairment in functioning after receiving antihypertensive therapy. Whether small changes, discernible only to relatives, will have long-term effects on compliance has not vet been determined.

#### **Economic Considerations**

While economic status is a component of functional capacity, this area is infrequently addressed in quality of life trials. Many unanswered questions remain regarding the economic aspects of quality of life. The following should be considered: (1) How may improved well-being be measured in economic terms, and (2) what will be the outcome if hypertensive patients cannot afford the more expensive medications such as captopril and verapamil? It should be recognized that the median annual income of patients in the study by Croog et al<sup>2</sup> was over \$30,000. The beneficial effects of captopril on quality of life may not be identical in patients who cannot afford the medication without significant sacrifice.

If patients cannot afford the cost of antihypertensive medications, the long-term effects on morbidity and mortality, as well as on quality of life, may be affected. <sup>14</sup> The economic impact of antihypertensive therapy should be carefully weighed before applying quality of life findings to the practice setting. <sup>15</sup>

#### PHARMACOLOGIC CLASS

The definition, measurement, and evaluation issues associated with quality of life data are important in their application to the practice setting. What is actually known, however, about the four first-line antihypertensive classes? Aside from the study by Croog et al,<sup>2</sup> most of the available information is based on the side effects reported from large-scale trials such as the Hypertension Detection and Follow-up Program. <sup>16,17</sup> It is important to recognize that side effects and quality of life findings are not equivalent.

#### **Diuretics**

Hydrochlorothiazide and related diuretics continue to be prescribed as initial antihypertensive therapy. Croog et al<sup>2</sup> have reported that the addition of hydrochlorothiazide to methyldopa, propranolol, or captopril therapy reduced patients overall sense of well-being. The specific quality of life effects of hydrochlorothiazide alone have not, however, been determined, and most of the available information is limited to adverse drug reaction reporting.

# β-Adrenergic Blockers

Currently there are eight  $\beta$ -adrenergic blockers that differ in such characteristics as lipophilicity, cardioselectivity, and intrinsic sympathomimetic activity. Propranolol, a nonselective lipophilic agent, possesses both positive and negative quality of life effects.<sup>2</sup> While work performance of patients on propranolol may be improved when compared with that of patients receiving methyldopa, sexual functioning and overall general well-being may be reduced with propranolol.<sup>2</sup> As a result of differences in lipophilicity and cardioselectivity, extrapolation from Croog et al<sup>2</sup> to atenolol or metoprolol is difficult.

Although central nervous system reactions associated with  $\beta$ -adrenergic blockers are not equivalent to quality of life effects, they deserve special attention. The side effects have ranged from drowsiness and lethargy to hallucinations and depression. The latter may be particularly important.

Recently, Avorn et al<sup>18</sup> reported the findings of a retrospective study to determine the prevalence rates of tricyclic antidepressant usage among a random sample of patients. The presence of a prescription for tricyclic antidepressants was used as a marker of depressive symptoms. The use of tricyclic antidepressants was significantly higher in patients receiving a  $\beta$ -adrenergic blocker than for those prescribed hydralazine or methyldopa over the two-year study period.

A major limitation of the study is that it did not examine the temporal relationship between the usage of the tricyclic antidepressant and  $\beta$ -adrenergic blocker; it is unclear which drug was actually prescribed first. Second, antidepressant usage was higher with nadolol than with propranolol. This finding is unexpected, as nadolol is hydrophilic.

Additionally in the early 1980s, ACE inhibitors and calcium antagonists were not prescribed for mild hypertension. If a patient was receiving a tricyclic antidepressant, and later was found to have hypertension, the available options for antihypertensive therapy were limited. Tricyclic antidepressants may interact with clonidine, guanethidine, and methyldopa. There may have been a bias, therefore, toward using  $\beta$ -adrenergic blockers in individuals already receiving antidepressant therapy.

Recently, several studies have compared the subtle central nervous system effects of  $\beta$ -adrenergic blockers. Gengo et al, <sup>23</sup> in a double-blind crossover study, compared the effects of atenolol to those of metoprolol on drowsiness and mental performance in older patients with mild to moderate hypertension. Twenty-seven patients aged between 55 and 90 years with a mean age of 63 years were enrolled in the study. After an initial placebo phase, each was randomized to receive either 100 mg of atenolol or 150 mg of metoprolol daily before being switched to the other  $\beta$ -adrenergic blocker. All study periods were two weeks in duration.

Drowsiness was assessed subjectively using a visual analogue scale and objectively by critical fusion frequency threshold testing. Mental performance was assessed using Trails-A testing from the Halstead Reitan battery.<sup>23</sup>

The findings of Gengo et al<sup>23</sup> indicate that, although there was objective evidence of lethargy, patients did not subjectively appreciate any change during  $\beta$ -adrenergic blocker therapy. Scores on the Trails-A testing actually improved as patients were switched from placebo to metoprolol. This improvement was not observed in patients who received atenolol. The authors concluded that significant drowsiness or mental impairment should not be expected to occur in older hypertensive patients receiving  $\beta$ -adrenergic blockers.

This study, as well as others,  $^{24,25}$  has challenged common beliefs about  $\beta$ -adrenergic blockers. There are, however, concerns about these findings and their application in primary care.  $^{26}$ 

The treatment periods may not have been sufficiently long to identify the actual effects of each  $\beta$ -adrenergic blocker. This study specifically lacked a washout period as well. It is unknown whether the observed results will be sustained during chronic therapy. In addition, the patient population consisted of older hypertensive patients with a mean age of only 63 years and none of the common co-existing diseases such as diabetes mellitus or chronic obstructive pulmonary disease. Is it possible to extrapolate these results to the 70-year-old hypertensive patient with mild co-existing ischemic heart disease?

# **Angiotensin-Converting Enzyme Inhibitors**

Captopril, enalapril, and lisinopril represent an important advance in the management of mild to moderate hypertension. Croog et al<sup>2</sup> have demonstrated that patients receiving captopril scored higher on measures of general wellbeing, work performance, visual motor functioning, and life satisfaction than individuals taking methyldopa. It is unknown whether these findings are applicable as well to enalapril and lisinopril, which are chemically, pharmacokinetically, and pharmacodynamically different from captopril.

In addition, any evaluation of the quality of life effects of captopril should take into account its cost. The cost to the patient for an ACE inhibitor such as captopril, 50 mg twice daily, may approach \$400 annually. This cost may be reduced by recognizing that the effectiveness of captopril in mild to moderate hypertension reaches a plateau at a dosage of 75 to 100 mg daily.<sup>27</sup> The addition of a small dose of a diuretic will frequently result in a marked increase in the effectiveness of the ACE inhibitor, especially in the older hypertensive patient, although selected measures of quality of life may be affected.<sup>2</sup>

# **Calcium Antagonists**

Nifedipine, diltiazem, and verapamil are generally well tolerated, with the majority of their adverse reactions the direct result of vasodilation. The influence of calcium antagonists on specific quality of life factors has not yet been studied. Recently Callendar et al<sup>28</sup> assessed selected quality of life effects in 30 hypertensive patients randomized to receive either nicardipine, an investigational calcium antagonist, or propranolol for 12 weeks after an initial placebo period. All patients demonstrated some degree of cognitive impairment with antihypertensive therapy. Neither group, however, had detectable changes in their overall sense of well-being or in their ability to fulfill social roles.

#### **FUTURE DIRECTIONS**

The eventual findings of the Treatment of Mild Hypertension Study (TOMHS) will provide further information regarding the comparative quality of life effects of different antihypertensive agents. TOMHS is a multicenter, randomized double-blind trial comparing intensive dietary therapy and five different drug regimens. <sup>29</sup> Study medications include chlorthalidone, acebutolol, enalapril, doxazosin (an investigational  $\alpha$ -1 inhibitor), and amlodipine (an experimental calcium antagonist). A total of 850 patients between the ages of 45 and 69 years with mild hypertension will be enrolled. Comparative quality of life effects, in addition to other measurements, will be determined.

#### SUMMARY

The management of mild to moderate hypertension has evolved from the traditional step therapy of diuretics and  $\beta$ -adrenergic blockers. Quality of life effects are becoming an important consideration in the selection of antihypertensive therapy for specific patients. Most of the available information, however, has been derived from one major

study. The evaluation of new antihypertensive medications should include quality of life assessments.

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# Commentary

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The above review by Hume¹ of the role of quality of life data in practice gives some sense of the progress that has been made in recent years in measuring and investigating the role of quality of life factors in clinical practice. While a role in the research arena is clearly established, the translation of such measures in clinical practice is still in its infancy. Most of the comment that follows focuses on the former.

Quality of life has emerged as a significant outcome

measure in evaluating health status in the last 15 years as the emphasis moves from a preoccupation with death or survival to many aspects of life and death. There is an increasing realization that there is more to life than not dying.<sup>2</sup> One of the achievements of the consumer movement in health care has been a move away from a physician-dominated preoccupation with biomedical outcomes to a patient-centered sensitivity to psychosocial aspects of health care.

While lifestyle changes are important in the aggressive management of most chronic diseases, the long-term use of pharmacological interventions is usually the backbone of management of such diseases as ischemic heart disease, hypertension, and diabetes. It has become apparent that quality of life issues play an important role in much of the noncompliance that plagues the long-term management of these chronic diseases.

In her review of quality of life factors in the management of hypertension, Hume<sup>1</sup> has focused on an area of clinical practice where quality of life issues have moved rapidly from the research arena into the world of pharmaceutical marketing. A differential impact of one hypertensive agent on quality of life<sup>3</sup> has been used as the clinical basis of a major marketing initiative. This finding has vastly increased interest in such quality of life outcome measures and has made available new sources of research funding from the pharmaceutical industry to this area of clinical research. Family physicians are particularly well placed to participate in or initiate these studies.

The studies reviewed by Hume<sup>1</sup> provide information about the relative importance of quality of life considerations in the choice of hypotensive agents. This information can be used alongside other data—for example, the cost of these same drugs or their relative impact on lipoprotein profiles—when a physician chooses a drug for his patient. In the Croog et al study,<sup>3</sup> the most expensive drug was the one with the least impact on quality of life.

There is also now much greater sensitivity to quality of life measures in the design of large drug trials where measures such as the Sickness Impact Profile, 4 activities of daily living,5 and psychological status6 are used to complement clinical outcomes such as chest pain, dyspnea, drug side effects, and electrocardiographic findings. Another important influence on the accelerating interest in quality of life outcomes is the work of Wennberg et al<sup>8</sup> on small-area variation in physician clinical decisions. As early as 1973 Bunker and Wennberg<sup>9</sup> were drawing attention to quality of life issues in relation to such discretionary or elective surgery as prostatectomy. Small-area variation studies have shown wide variability in physicians' use of major procedures. Large-scale initiatives supported by the National Center for Health Services Research are currently getting under way in the evaluation of clinical outcomes including quality of life outcome measures. Before one can develop or evaluate any valid and reliable measure of quality of life, some kind of agreement is needed as to the definition of this familiar but ambiguous clinical construct.10

# What Is Quality of Life?

Hume defines quality of life as an individual's perceived ability to function normally within society.<sup>11</sup> More spe-

cifically, she includes functional capacity, perceptions, and symptoms. This definition equates quality of life with successful adaptation or functioning. She includes in her definition not only biomedical, psychological, social, and role functioning, but also cognitive functioning and economic well-being. She emphasizes the importance of positive as well as negative psychological functioning.

This definition of quality of life is a very broad one. The value of such a definition is its comprehensive perspective on the patient's life. The difficulty in using it is that a single measure covering all these facets of functioning is very unwieldy and presents significant analytic problems in scoring. If one overall score for quality of life is desirable, then decisions must be made on the relative importance of one dimension, such as economic well-being, over another, such as positive psychological health.

In defining quality of life, one must first relate it to other closely related and overlapping constructs. There is considerable dispute as to the interrelationships among such concepts as quality of life, health status, and patient functioning. Spitzer<sup>12</sup> has suggested that the term *health status* be reserved for studies of normal populations in good health, while *quality of life* be used for studies of the impact of illness on those who are truly ill. Between these he places a third category, which he calls *hypothesis-determined functional measures*, where the emphasis is on measuring the impact of therapeutic interventions. The studies reviewed by Hume fall into this last category.

# **How Do We Measure Quality of Life?**

Having decided that quality of life is an important variable in a research project, we must then decide how to measure it. Since measurement implies an instrument, we must choose an appropriate one. We must then decide whether to use an existing one, to modify an existing one, or to create a new one. Feinstein et al, 13 in a very wide-ranging review of the measurement of functional disability, have noted that at least 43 different measures exist to record activities of daily living, and of these, 15 have been published in the last decade. This large number highlights the continuing need to assess these aspects of patients' functional status but implies there are many different perspectives on how to do so. In this same review Feinstein et al have observed that most new indices are justified in their initial publications by the failure of existing measures to meet the specific needs of the investigators.

A new measure of patient functioning for use with diabetic patients has recently been developed at the University of Washington. After a comprehensive review of existing measures had failed to identify one appropriate for the research project, it was decided to use selected subscales of existing well-established and validated measures. Ware's definition<sup>14</sup> of patient functioning was used

to identify the key dimensions in the measure and to identify possible subscales in existing measures that would fit each dimension. Factor analysis was used to identify the most appropriate and discriminating subscales for each dimension. The principal hypothesis in this project was that the more intensive the diabetic control regimen, the more dysfunction it would induce in the patient. This new measure, the Generic Patient Functioning Profile,\* (GPFP) was used to compare three cohorts of insulindependent diabetics on regimens of varying intensity who had been stabilized on their regimens for at least one year. This analysis revealed no difference in functioning among the three regimens. To make the GPFP profile more accessible for clinical use, a microcomputer-abbreviated version was developed using the most discriminating subscales from the larger profile instrument. This application combines a modification of existing measures with the development of a project-specific instrument.

The third alternative, as noted above, would be to use existing measures. A number of well-validated generic measures are available. Among the most widely used are the Sickness Impact Profile (SIP)4 and the Duke-UNC Health Profile, 15 which was specifically developed for use in primary care settings.3

# Validating a Measure

Spitzer<sup>12</sup> has called for a set of minimum criteria necessary for adequate validation of quality of life measure so that the very variable level of validation found in published studies can be improved. He suggests that these criteria should include performance characteristics for (1) content validity including input by patients, providers, and the general public, with reliability being verified by those who will eventually use it, (2) establishing criterion validity where a "gold standard" exists using the same input by users as in 1, or (3) using construct validity (where criterion validity does not exist) with at least one approach each for both discriminant and convergent validity. He strongly favors patient involvement in all of these validation studies.

studies may not be appropriate for use in investigating

Can the Measure Detect Meaningful Change? If an instrument is to be of any value in a research project, or even more, if it is to have any impact on clinical practice, it must be able to detect clinically meaningful change. This property of a measure is usually called its clinical sensitivity. Measures developed for use in population

clinical issues. Similarly, most measures are developed for providing moment-in-time information, which may not always be adequate for answering clinically based research questions. 16 For example, MacKenzie et al 17 found that the Sickness Impact Profile was unable to detect improvement and deterioration in functional status equally and was limited in its usefulness for following individuals over time. Lee et al<sup>18</sup> developed an index to measure joint function in patients with rheumatoid arthritis. It had high interrater and intrarater reliability and was found to be useful for single-state assessments but not for detecting clinically meaningful change. Thus it was able to detect improvement following major joint surgery but not that following the administration of anti-inflammatory agents in short-term clinical trials. Deyo and Inui<sup>19</sup> studied the sensitivity of the Sickness Impact Profile to clinically meaningful changes in patients with rheumatoid arthritis. In their studies the estimates of clinical changes were independently agreed upon by both the physician and the patient. The predictive accuracy of the Sickness Impact Profile for estimating such change was low against both the above clinical assessments and when several different indices of disease severity were used as criteria of change. Klein and Bell<sup>20</sup> have tackled this issue of clinical sensitivity by specifically developing a clinical index sensitive to small changes in activities of daily living. This index has been shown to have high interobserver and intraobserver reliability.

#### Reducing the Number of Items in Measures

There seems to be a consensus emerging that some attempt should be made to simplify and shorten measures so as to facilitate their use in the clinical environment. Ware<sup>14</sup> has conducted an extensive review of data on patient functioning and has proposed a framework for organizing measures of functioning involving several relatively independent dimensions. These measures include four dimensions of functioning and one disease-specific dimension related to the disease being studied. The proposed dimensions are as follows:

- 1. Disease-specific measure of biomedical function (eg. mean fasting plasma glucose level in diabetes mellitus or an articular index in rheumatoid arthritis)
  - 2. Physical functioning (eg, activities of daily living)
- 3. Emotional functioning (eg, psychological distress or well-being)
  - 4. Social functioning (eg, performance of social roles)
  - 5. General health perceptions

This framework will be very useful for making comparisons and eliminating redundancies among measures. It was used in Ware's study<sup>14</sup> and those undertaken by the

A copy of this instrument is available from the author on request.

diabetes research group at the University of Washington mentioned earlier. A complementary approach to reducing the size of measures is to simplify existing well-validated ones. A good example is the Duke-UNC Health Mini-Profile (Mini-DUHP), a ten-item subset of the original 63-item Duke-UNC Health Profile. The reliability and validity of the Mini-DUHP has been demonstrated by Blake et al<sup>21</sup> in a primary care setting. The aim in reducing the number of items was to make the profile more useful clinically.

# Research Applications of Quality of Life Measures

To date, all applications of quality of life measurements have been in the research arena. The main nonclinical uses of measures of functional status have been (1) determining compensation, (2) predicting prognosis, (3) estimating care requirements, (4) choosing types of specific care, and (5) monitoring changes in status. The main clinical uses of quality of life measures have been for (1) establishing the initial clinical database, (2) following the natural progression of chronic diseases, such as rheumatoid arthritis or diabetes mellitus, and (3) choosing among therapies such as hypotensive agents. <sup>13</sup>

# **Using Quality of Life Data in Clinical Practice**

Despite increasing interest and activity in the research arena, little impact has been seen in clinical practice. Thus in a recent study of the use of the Sickness Impact Profile in a clinical setting, where it was completed by both patient and physician before the clinical encounter, 16 only one half of the physicians felt it would be useful in clinical management. A chart audit six months after the experiment found little or no impact on patient care in terms of patient referrals to other physicians, allied health personnel, or agencies or in return visits to the physician. If we wish to be able to incorporate quality of life information into the day-to-day management of patients, then much progress need to be made in our approach to measuring it, in incorporating the perspective of the patient, and in understanding differences in practice styles among clinicians.<sup>22</sup> Future emphasis in the design of quality of life measures must more explicitly involve the perspective and preferences of patients. Thus an elderly patient may be much more concerned about being able to resume knitting as a recreational activity than in participating in social activities with others. Similarly, a significant number of diabetic men have been shown to be much more concerned about impotence than about the threat of blindness resulting from retinal neovascularization.

Measures that are to be routinely incorporated into clinical practice must be compatible with the context in

which the decisions that they are going to influence are being made. This context may be a nursing home or a busy inner-city practice: hence the importance of reducing the length of instruments. Some instruments should be self-reported by patients, whereas others might appropriately be completed by physicians or other caregivers after observation of the patient in his or her familiar environment.<sup>12</sup>

In the future as computers become commonplace in office settings, the assessment of quality of life will be incorporated into the clinical decision support systems that are emerging for primary care use. These support systems will function as often as not as *aides mémoire* to physicians who want to make relevant and comprehensive assessments of their patients in a systematic and reliable way. Since physicians differ widely in their practice styles, as Wennberg<sup>22</sup> has demonstrated, different versions of the same instrument may be necessary to fit the differing cognitive styles of physicians to make the assessment of quality of life and functional status as widespread and appropriate as possible in the future.

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