The treatment of hypertension is long-term and is directed towards the reduction of mortality and morbidity, especially from stroke and heart disease (CHD). Although treatment undoubtedly reduces strokes, and to a lesser extent CHD events, there are a variety of unresolved issues. These include what levels of blood pressure should be treated, whether indications for treatment should also include prognostic factors such as age, gender, and the presence of other cardiovascular risk factors, which treatment to use (including non-pharmacological approaches), adverse effects and the monetary costs of treatment. Adverse effects include factors which may affect morbidity, such as elevated blood lipids, uric acid, glucose intolerance, and more diffuse side-effects which impair well-being, and may cause patients to discontinue treatment. In the trial of the European Working Party on High Blood Pressure in the Elderly (EWPHE) it was calculated that in every 1000 patients treated for one year, active treatment (a potassium sparing diuretic combination, plus methyldopa in one third) was associated with an excess over placebo of four cases of gout, 23 of an abnormal serum creatinine, nine of diabetes, 124 with a dry mouth and 71 complaining of diarrhoea. In this trial there were relatively few withdrawals due to side-effects. In contrast over the 5 years of the Medical Research Council trial, 16% of patients on active treatment had withdrawn owing to side-effects: impotence, lethargy, nausea, dizziness and headache were the major reasons.

Active treatment was discontinued in 9% of patients for definite side-effects over the 5 years of the Hypertension Detection and Follow-up Program (HDFP) and in a further 23% for possible side-effects. Eight percent of all male patients discontinued treatment because of sexual problems. Lethargy and gastrointestinal symptoms were the commonest reasons for discontinuation (4–6%) in all patients.

Psychological well-being may also be affected both by drug treatment and by labelling the patient with a diagnosis of hypertension. Studies have
suggested impairment of memory and learning ability in both treated and untreated hypertensives\textsuperscript{14,18,27,28}.

Earlier case-reports indicated an association between depression and beta-blocker therapy in hypertensive patients, ranging from 0.1 to 6\%\textsuperscript{26}. More recently, an excess use of tricyclic antidepressants was found in patients on $\beta$-adrenoceptor blocking drugs compared to other forms of anti-hypertensive therapy in a large random sample of Medicaid recipients\textsuperscript{1}.

Although all these studies suggest impairment in quality of life due to side-effects of treatment, a more precise evaluation and quantification of the effects of therapy is required. In the next section we will discuss some of the issues involved in the measurement of quality of life in trials of anti-hypertensive therapies.

**WHAT ASPECTS OF QUALITY OF LIFE SHOULD BE MEASURED?**

Some authors advocate the investigation of a whole constellation of variables which have been shown to be important in determining quality of life\textsuperscript{21,24}. This would include determination of:

- **Demographic** variables such as work, educational income, status, social membership and participation in social and family groups, work satisfaction, and the ability to feel a worthwhile member of a group\textsuperscript{17}. The pursuit of leisure time interests is also relevant in Western society. Social support has been shown to be an influential factor in the maintenance of health\textsuperscript{3}.

- **Psychological**: emotional level, psychiatric morbidity, intellectual performance, ability to perform tasks, loss of libido.

- **Physical** performance of the individual at work, aspects of self-care such as bathing and dressing, mobility and confinement.

- **Spiritual**, namely the ability of the individual to transcend everyday life by aesthetic or religious experiences.

It may be argued that, ideally, long-term and comprehensive evaluation of the effect of antihypertensive treatment on quality of life should include all the above components. There are, however, serious restrictions to this approach in terms of the feasibility, design and costs of such a study: a large battery of tests and questionnaires would be needed requiring a variety of specialist training staff. Also, patients may be reluctant to undergo several hours of tests and many measures, for example social support, are unlikely to be sensitive to the short term effects of drug treatment. When a quality of life evaluation is included in trials primarily designed to assess the efficacy of drugs in lowering blood pressure, only those variables that are likely to be fairly immediately responsive to the effect of a drug should be included.

It is unlikely that any major demographic changes would occur over a short period, even if the treatment did, in fact, improve the patient's physical and