

meeting of the Association of British Neurologists in April 1992. We thank Professor Charles Warlow for his helpful comments.

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(Accepted 1 September 1992)

## Quality of life measures in health care. I: Applications and issues in assessment

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### Summary

Many clinicians remain unsure of the relevance of measuring quality of life to their clinical practice. In health economics quality of life measures have become the standard means of assessing the results of health care interventions and, more controversially, the means of prioritising funding; but they have many other applications. This article—the first of three on measuring quality of life—reviews the instruments available and their application in screening programmes, audit, health care research, and clinical trials. Using the appropriate instrument is essential if outcome measures are to be valid and clinically meaningful.

Interest in measuring quality of life in relation to health care has increased in recent years.<sup>1,2</sup> The purpose is to provide more accurate assessments of individuals' or populations' health and of the benefits and harm that may result from health care. The term quality of life misleadingly suggests an abstract and philosophical approach, but most approaches used in medical contexts do not attempt to include more general notions such as life satisfaction or living standards and tend rather to concentrate on aspects of personal experience that might be related to health and health care. Some of the commonly used synonyms for quality of life more accurately convey the content and purpose of measures—health related quality of life, subjective health status, functional status. This is the first of three papers intended to review measurement issues surrounding the use of the growing number of questionnaires and interview based instruments designed to assess health related quality of life.

### Alternative applications

Quality of life measures can be used in many ways in health care (box 1). For example, quality of life instruments have been shown to be better than conventional rheumatological measures as predictors of long term outcomes in rheumatoid arthritis in terms of both morbidity and mortality.<sup>3,4</sup> They can therefore be used to identify patients needing particular attention. They may also be used to screen for psychosocial problems; to monitor patients' progress, particularly in relation to the management of chronic illness; or to determine choice of treatment.

Several studies have shown that clinicians' and

### Box 1: Applications of quality of life measures

- Screening and monitoring for psychosocial problems in individual patient care
- Population surveys of perceived health problems
- Medical audit
- Outcome measures in health services or evaluation research
- Clinical trials
- Cost-utility analyses

patients' judgments of quality of life differ substantially and systematic assessment may improve health professionals' judgments.<sup>5,6</sup> Clinicians seem to find the information from quality of life measures useful and informative but trials have found that the additional information does not greatly alter clinical decisions or short term changes in health status.<sup>7,8</sup> These disappointing results may arise either because the quality of life data are inappropriate to clinical decision making or, more likely, because the information is not fed back to clinicians in the most useful format or at the right time.

Quality of life measures used for screening need to be evaluated in terms of sensitivity (false negative results) and specificity (false positive results). Instruments whose value has been proved for screening should not be assumed to be effective for other purposes—for example, as outcome measures in trials or in evaluation studies. A recent conference on applications of quality of life instruments in routine patient care concluded that, in the United States at least, many practitioners have a mixture of enthusiasm for their potential relevance to clinical practice and unresolved doubts.<sup>9</sup>

### POPULATION APPLICATIONS

Quality of life instruments can also be used in surveys of the health of district or general practice populations. Such instruments can assess subjective aspects of health problems not addressed by conventional epidemiological measures.<sup>10</sup> Here too, however, it is not yet clear how useful quality of life information will prove in assessing health needs.<sup>11</sup>

In more formal studies of health service research quality of life assessments provide an important

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BMJ 1992;305:1074-7

outcome measure.<sup>12</sup> Increasingly it is argued that quality of life measures should be incorporated in medical audit.<sup>13</sup> Certainly, they provide information that is relatively economical to gather and process for audit purposes. Unlike much audit data, quality of life focuses on outcomes and patients' concerns. One of the few studies in Britain to examine the application of quality of life data to regular hospital medical audit gave encouraging results. A demonstration project at the Freeman Hospital, Newcastle, was successful in setting up a routine system to collect outcome measures including quality of life assessments in a way that was acceptable to clinicians and managers.<sup>14</sup> The feasibility of routine use of quality of life instruments has also been shown in several health care settings in the United States, although these studies suggest that considerable attention has to be given to integrating data gathering into clinic and surgery routines and making data readily intelligible to busy clinicians.<sup>15 16</sup>

### Clinical trials

The best understood application of quality of life measures is in clinical trials, where they provide invaluable evidence of the effects of interventions. Unfortunately, many trials purporting to assess impact of treatment on quality of life do not assess the construct properly or assess a single or limited aspect of what is a multidimensional construct.<sup>17</sup> Moreover, multidimensional end points such as quality of life present particular problems of design, analysis, and interpretation.<sup>18</sup> These problems are considered in our second paper. The most controversial use of these measures is in health economics, where quality of life seems to provide a single standard means of expressing the results of health care interventions in cost-utility analyses. In our third paper we consider this application, widely associated with the technique of calculating quality adjusted life years (QALYs).

It is important to distinguish the different applications of quality of life measures because instruments that have proved useful when applied in one context may be less appropriate elsewhere. A good research tool may be impractical for clinical uses. Generally, more attention has been given to the use of quality of life instruments in clinical trials than to examining their value in routine clinical care, medical audit, or resource allocation.

### Definitions, dimensions, instruments

Although the concept of quality of life is inherently subjective and definitions vary, the content of the various instruments shows some similarity (box 2). Early measures of patients' function or general wellbeing such as the functional scale of the American Rheumatism Association<sup>19</sup> or the Karnofsky index,<sup>20</sup> tended to use a single score. Now many instruments reflect the multidimensionality of quality of life. A person may be confined to a wheel chair with little range of movement but have a strong psychological

wellbeing or sense of social support. This diversity of experience cannot be captured in a single scale.

There are two basic types of instrument, disease specific and generic. Disease specific instruments have been developed for one disease or a narrow range of diseases. Examples include the arthritis impact measurement scales<sup>21</sup> and the back pain disability questionnaire.<sup>22</sup> Generic instruments are intended to be applicable to a wide range of health problems. Among the more commonly used are the sickness impact profile<sup>23</sup> and the Nottingham health profile.<sup>24</sup> For cancer modular format instruments have recently been developed, which comprise a core of general purpose quality of life items together with more specific instruments designed for each of the main types of cancer.<sup>25</sup>

Though some instruments are administered by clinicians or interviewers, increasingly the emphasis has been on self completed questionnaires for each and economy of use. The quantitative information provided also varies. Most give scores for the different dimensions of quality of life which are not intended to be combined but others assess dimensions that may be summed to provide a single score. Thus the QL index, developed for use in patients with cancer, consists of items on five dimensions (activity, daily living, health, support, and outlook) which are summed to provide a QL index total.<sup>26</sup> Summing disparate dimensions is not recommended because contradictory trends for different aspects of quality of life are missed.

### Requirements of measures

#### RELIABILITY

All instruments must produce the same results on repeated use under the same conditions. This can be examined by test-retest reliability, although practically it may be difficult to distinguish measurement error from real changes in quality of life. Reliability is often assessed by examining internal reliability—the degree of agreement of items addressing equivalent concepts. Inter-rater reliability also needs to be established for interview based assessments.<sup>18</sup>

#### VALIDITY

The validity of quality of life measures is more difficult to assess because instruments are measuring an inherently subjective phenomenon. An informal but essential approach is to examine face validity by asking whether instruments seem to cover the full range of relevant topics. This process may be enhanced by including people with a wide range of backgrounds in the assessment process—for example, doctors, nurses, patients, social scientists.<sup>27</sup> In addition in depth descriptive surveys of the relevant patient group should be consulted as these provide invaluable evidence of the range of patients' experiences.<sup>28</sup>

A more formal approach is to examine construct validity, which is concerned with the pattern of relations of the quality of life instrument with other more established measures. This may require examination of the extent of agreement of quality of life scores with laboratory or clinical measures of severity of disease<sup>29</sup> or of the ability of the instrument to distinguish between patient groups considered to have different health statuses.<sup>30</sup> Exact agreement with other measures, such as severity of disease, is not required since that would mean that quality of life scores were redundant. Above all, once validity has been shown for one purpose it cannot be assumed for all possible populations or applications. For example, an instrument validated for rheumatoid arthritis and subjective problems in the areas of pain, mobility, and fatigue gave scores for pain that were too low when applied to patients with severe migraine.<sup>31</sup> This was an artefact of

#### Box 2: Dimensions of quality of life

- Physical function—for example, mobility, self care
- Emotional function—for example, depression, anxiety
- Social function—for example, intimacy, social support, social contact
- Role performance—for example, work, housework
- Pain
- Other symptoms—for example, fatigue, nausea, disease specific symptoms



the instrument's approach to measurement, which emphasised pain associated with movement, a problem characteristic of locomotor disorders but not of headache.

#### SENSITIVITY OF CHANGE

Measures of quality of life that can distinguish between patients at a point in time are not necessarily as sensitive to changes in patients over time when repeated. However, sensitivity to change, sometimes referred to as responsiveness, is a crucial requirement for most applications, especially in clinical trials, evaluation research, or cost-utility analyses. There are several reasons why instruments may be insensitive to change in quality of life. One reason is that larger more generic instruments may include several items not relevant to the particular disease or treatment group.<sup>32</sup> A second related factor is that instruments may include items that assess areas that are relatively static or not a feasible target of the health care intervention—for example, patterns of social relationships.<sup>33</sup> A third problem is that quality of life measures may be subject to ceiling or floor effects. For patients with very poor quality of life who obtain minimum scores before treatment there may be no scope to register any further deterioration.<sup>34</sup> Finally, some quality of life instruments still contain too few broad categories to be sensitive to subtle but important changes in patients.<sup>35</sup> It is not surprising therefore that when patients complete several quality of life instruments a different impression of quality of life changes over time may be obtained with different measures.<sup>36 37</sup>

The absence of a standard against which to assess the measurement properties of a quality of life instrument is a particular problem when examining instruments' sensitivity to change. One approach is to examine the associations between quality of life change scores and other changes in health status.<sup>38</sup> The alternative is to examine the sensitivity and specificity of quality of life change scores against an external criterion such as the view of the clinician or the patient that a significant change has occurred.<sup>35 39</sup> However, one of the most important areas for further development is in making quantitative change scores for quality of life more clinically meaningful.

#### APPROPRIATENESS

To ensure that the quality of life measure used is the most appropriate, the health problem and likely range of impacts of the treatment being investigated need to be carefully considered. Sometimes the possible side

#### Box 3: Basic requirements of quality of life assessments

- Multidimensional construct
- Reliability
- Validity
- Sensitivity to change
- Appropriateness to question or use
- Practical utility

effects of treatment on quality of life cannot be predicted and investigators use wide ranging quality of life measures to uncover unexpected problems.<sup>40</sup> A "scatter-gun" approach clearly has problems, in particular the large volume of data generated, burdens on patients, and the risk that results will prove significant by chance because of the number of variables tested.

Established instruments can not be assumed to be the most appropriate. One of the instruments most often used to assess quality of life in rheumatoid arthritis—the arthritis impact measurement scales<sup>21</sup>—does not assess fatigue, a dimension that patients report as one of the most distressing consequences of the disease.<sup>41</sup>

The importance of different dimensions of quality of life varies among individuals and the instrument should reflect patients' priorities and preferences. In one study of women with metastatic breast cancer most women regarded issues such as self care, mobility, and family relationships as of greater concern than side effects of treatment.<sup>42</sup> One approach to improving the appropriateness of quality of life measures is to use instruments that let patients select the dimensions of most concern. This baseline of quality of life scores, which will vary from patient to patient, can then be used in assessing changes over time.<sup>43</sup> There is some evidence that this approach may produce greater sensitivity to change over time than conventional standardised measures.<sup>44</sup>

#### PRACTICALITY

At present quality of life measures are most practical for use in clinical trials and formal evaluation studies, where they are used alongside other information about patients, treatments, and outcomes to address fairly precise questions. Even in these contexts greater effort is needed to make quality of life data clinically meaningful.<sup>45</sup> For regular use in clinical care or medical audit the more detailed and comprehensive measures of quality of life are both impractical to administer and process and hard for health professionals to interpret and incorporate into decision making. Instruments that are to be used routinely need to be briefer and simpler to use.<sup>44</sup> Several instruments such as the Dartmouth Coop charts<sup>45</sup> and medical outcome study short form general health survey<sup>46</sup> have been developed with such practical concerns in mind. Brevity may mean that potentially important information about patients' experiences is missed and the validity and responsiveness of shorter instruments need to be studied. Just as important is the need to examine ways of incorporating brief assessments into provision of health care.<sup>43</sup> Particularly important is the value to patients of such information. One of the few studies to consider this issue found that patients liked completing such questionnaires and thought that the information was important for their doctor to know.<sup>47</sup>

In clinical trials many scientific questions cannot be answered properly without adequate measurement of quality of life. It is disappointing, therefore that, even in this best understood of applications, many trials either omit quality of life measures altogether or use



J.L. PETIT/COLORSPORT

*Quality of life is multifactorial. Being in a wheelchair doesn't preclude a satisfying life*

inappropriate assessments.<sup>48</sup> This may stem partly from erroneous concerns about the lack of reproducibility of interview or questionnaire based data compared with hard conventional measures.<sup>49</sup> In addition data from quality of life measures are unfamiliar and lack the intuitive meaning of more established clinical or laboratory measures. Providing that careful attention is given to six basic issues (box 3), it is feasible to assess health related quality of life. Outside clinical trials fundamental concerns about quality of life as applied to health care have emerged regarding ethical and political ramifications of the use of the concept in relation to resource allocation. We will consider the issues behind such concerns in a later paper.

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(Accepted 9 September 1992)

## ANY QUESTIONS

*Should a woman taking the combined contraceptive pill who contracts hepatitis A and has abnormal results of liver function tests be advised to stop taking the pill?*

Yes. The latest datasheets contraindicate oral contraceptives in women with abnormal liver function test results or acute or severe chronic liver disease.<sup>1</sup> Ingestion of contraceptive steroids alters hepatocellular function, and observable effects include changes in the composition of bile, reduced volume of biliary secretion, a rise in cholesterol concentration, and a fall in the bile acid level. These changes are reversible and dose related.<sup>2</sup> Thus in

patients with already deranged liver function it would be advisable to avoid the combined oral contraceptive. In such cases the liver's metabolic and excretory function will probably also be impaired, and even with a low dose oral contraceptive the pharmacological effects may be unpredictable and greater than those in a woman with normal liver function.—P B TERRY, consultant in obstetrics and gynaecology, Aberdeen

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