

Book Review

Quality of Life Assessment in Clinical Trials

Bert Spilker (Editor)

Raven Press, New York, 1990

470 pages

Published in 1990 this remains a valuable bench book for any researcher involved in quality of life (QOL) assessment in clinical trials. Text books published in recent years have tended to focus on a single disease group, e.g. cancer patients, or have sought to provide a compendium of suitable measurement tools, but Spilker has accepted a broader brief. He draws together a review of the state of the art, which includes discussion of general and specific topics in QOL assessment from a range of perspectives most notably integrating economic concerns with clinical and psychometric issues. There is a great deal of redundancy particularly in the discussion of basic concepts and with the time which has elapsed since the book was first prepared, experienced clinical investigators will find little new information in the chapters covering their area of expertise. However, in a field where continuing progress depends on greater cross-fertilisation of ideas across specialties, the chief value of this book for many readers will be for the ease of access it offers to discussion of issues overlapping with but not central to their main research interests.

The 32 chapters are organised in five sections. The first provides an introduction to general concepts and approaches, and although there is considerable redundancy in this section each chapter justifies its place with some unique contribution underlining the continuing lack of consensus in the theoretical basis for QOL assessment.

Spilker's own brief introduction for example offers a useful graphic model of how the costs and benefits of medical treatment impinge on individual patients to influence their QOL. A more expansive introductory chapter by Schipper *et al.* reviews five conceptual formulations of QOL, ultimately proposing that

assessments focus on the by now familiar components of somatic sensation, physical function, psychological state and social interaction. By contrast Fries and Spitz suggest a hierarchical model of patient outcomes: i.e. death, disability, discomfort, iatrogenic and economic. Disappointingly they only elaborate on the disability index of their Health Assessment Questionnaire as a measurement tool. Chapters 4 and 5 by Guyatt and Jaeschke provide a sound basis for making an informed choice of appropriate measures and when a more specific measure is needed for developing and validating a new instrument. It is doubtful whether a novice in test construction could proceed on the basis of this chapter alone, but its inclusion lends substance to the often repeated caveat against the proliferation of *ad hoc* measures.

Section II deals with standard approaches to QOL assessment. The first of these by Grabowski and Hansen clearly presents the pros and cons of three economic approaches. The problem with the frequently used assessment of loss of productivity is that it reflects work activity not QOL *per se*, and satisfactory models of patients willingness to pay for changes in QOL have yet to be developed. The authors are optimistic even though available estimates based on opinions are subject to numerous sources of bias and are not highly correlated with what people actually do. Feeny *et al.* (chapter 7) offer a realistic discussion of how economic evaluations and QOL assessment may be integrated in clinical trials in future. The following three chapters are more standard reviews of measurement issues, in particular QOL dimensions.

It can be argued that social function in being interactive with others lies without the remit of health status measurement, but where physical appearance and/or body image are affected the impact on patients social activity may be an important outcome distinguishing otherwise equally efficacious treatments. Guadagnoli and Mor's pragmatic review of measures of social function is therefore a welcome though rather brief

inclusion (chapter 8). Shumaker *et al.* had a difficult brief in covering the vast topic of psychological measures and the inevitable selection process was bound to disappoint by omission. It was for example curious that the widely used Hospital Anxiety and Depression Scale was not mentioned. Chapter 10 provides an admirably succinct summary of current practice in the assessment of functional disability. In the absence of a model for integrating these different dimensions Kaplan and Anderson (chapter 11) propose a General Health Policy Model based on their Quality of Wellbeing scale to quantify outcomes in a single index of well-years. More empirical studies are needed to validate some of the assumptions made in this controversial model.

Section III covers special perspectives on QOL assessment which are rarely brought together in a single volume and was the section which I found most interesting. Levine (chapter 12) suggests criteria for determining an ethical need for QOL assessment in clinical research and Campos and Johnson (chapter 13) argue that with growing global interest in this field the need for culturally sensitive assessments has never been greater. This point is well recognised in the work of the EORTC Study Group on Quality of Life and in the more recent Euro QOL and WHO QOL initiatives. The remaining chapters of this section focus on the interests of the pharmaceutical industry from the marketing perspective (Morris, chapter 14) from the point of view of corporate policy (Henderson-James and Spilker, chapter 15) and finally with regard to regulatory requirements (Shoemaker *et al.*, chapter 16). Given that the pharmaceutical industry is increasingly sponsoring QOL assessment in clinical trials, the insights of these chapters will be particularly useful for academics and clinicians negotiating an interface with industry.

Section IV deals with QOL assessment issues in special populations. To some extent the allocation of topics to this or the following section "Specific Problems and Diseases", appears somewhat arbitrary and

there is again considerable overlap between chapters.

The measures hitherto discussed are unlikely to be suitable in paediatric populations (Rosenbaum *et al.*, chapter 17) where assessments may need to be completed by professionals or parents rather than by the children themselves and where developmental change makes it unlikely that a single measure will be appropriate across all age groups. This underlines a point of universal relevance which is often ignored that the research question i.e. the purpose of the QOL measurement should determine the selection of the appropriate assessment method. Two somewhat overlapping chapters emphasise comparable importance of attending to individual differences in needs among elderly patients generally (Williams, chapter 18) and the frail elderly in particular (Fretwell, chapter 19), if high quality care is to be offered to this group of patients who have in the past been excluded from therapeutic trials on the grounds of their age.

Metzger and O'Brien (chapter 20) summarize the challenge of assessing QOL among patients who abuse alcohol or other substances. Although identifying four potentially useful measures, they point to the need for the development of others which will be more responsive to the issues associated with the changing drugs of abuse e.g. 'crack'. They also draw attention to the need for independent validity testing of self-report data, which is a particular issue in this patient population. The chapter (21) by Turner on rehabilitation is particularly comprehensive, offering a three-dimensional model which takes account of the type of measurement (evaluative, predictive, discriminative) and the level of assessment (organic, individual, social) as well as of QOL dimensions (physical, mental, emotional, social). Five assessment scales suitable for use in this setting are reviewed in the light of this model with a discussion of issues surrounding their practical application. The complexities of chronic pain management as seen in a specialist pain clinic are summarized by Lee and Rowlingson (chapter 22) but their emphasis on the need for a multidisciplinary approach is also relevant to assessments of the impact of pain on the QOL of pati-

ents in other settings. Sensory, affective, behavioural and functional aspects need to be considered; intensity and frequency require to be distinguished and the timing of assessment in relation to therapeutic interventions is critical. Given the prevalence of pain as a problem and its relevance to patients QOL it is surprising how often it is poorly assessed in clinical trials and this point could usefully have been addressed in the text.

Raczynski and Oberman (chapter 23) provide a thorough review of the impact of coronary artery bypass grafting on patients QOL, including the often neglected issue of impact on neuropsychological function. In spite of the paucity of randomised control trials, the authors suggest that available data is sufficient to support the view that CABG improves QOL for the majority of patients and that future QOL assessment should be directed to evaluating the impact of post-surgical rehabilitation. However, given more recent work on the rehabilitation of patients following myocardial infarction and some questions about the criteria for the selection of patients for surgery, it may be that this conclusion is premature. Chapter 24 (McLeod) clearly gives a surgeon's perspective on the QOL issues for patients undergoing gastro-intestinal surgery, but it also displays some misconceptions about the psychometric basis for questionnaire assessment methods and on balance contributes relatively little additional information to the more detailed coverage of inflammatory bowel disease in the next section (chapter 28).

Section V entitled 'Specific Problems and Diseases', focuses on QOL issues for eight disease groups. Although some potentially interesting topics have been omitted e.g. gynaecological disorders, diabetes, the main bodily systems are represented. Inevitably the coverage is rather patchy.

There has been a problem in this field of ill-defined goals leading to unrealistic expectations of QoL assessment. Wenger and Furberg (chapter 25) usefully spell out a rationale for QoL studies in cardiovascular disorders which is operationally quite distinct for different subsets of patients and make a useful point about patients (and families) expecta-

tions, anticipating more recent work on the distinction between affective and cognitive components of QOL assessment.

The chapter on neurologic illness (chapter 26, Wilson Goetz) is somewhat disappointing given the prevalence of neurological problems, in other patient groups, the impact of neurological problems particularly of higher mental function, on quality of life and the concerns that non-specialist have about conducting assessments in this field. It was however interesting to have the problems of severe mental illness (chapter 27, Lehman and Burns) encompassed since contemporary socio-economic and political decisions about the care of these patients raise quality of life issues which are rarely embraced in texts focusing on physical illness. However, this chapter is presented in the style of a compendium of measures with only a brief discussion of the issues specific to this patient group.

Chapter 28 (Garret *et al.*) offers good coverage of the QOL issues and attempts made to assess them among adult patients with inflammatory bowel disease. My only regret about this chapter was that the authors missed the opportunity to discuss the problems of adolescence with Crohn's disease whose growth and maturational development is thereby compromised. This is an important issue for their QOL relative to age-matched peers and one which is shared with adolescents with other chronic diseases e.g. cystic fibrosis. Kaplan de Nour (chapter 29) summarizes lucidly the QOL issues in renal replacement therapies, pointing out that the psychological status of these patients has been exhaustively studied, although with methodological flaws and conflicting findings while in contrast to other disease groups relatively little attention has been given to patients physical and role functioning. The point is well made that over-testing of these patients, particularly if efforts are misdirected, compromises compliance of a patient group whose need for expensive and limited material resources remain the subject of constant scrutiny. Chapter 30 on chronic obstructive pulmonary disease is more comprehensive than some of the others and particularly satisfying for taking time to review

sensitive or difficult topics such as sexual functioning or social support, which other authors have omitted. The authors (McSweeny and Labuhn) also address the issue that by their own behaviour i.e. smoking, patients in this population contribute to their own disease, although the impact of smoking cessation attempts on QOL is not addressed. Given my personal interest in the QOL of cancer patients and the remit of this book, chapter 31 on cancer by Barofsky and Sugarbaker, was always going to be one reviewed most critically. The impact of cytotoxic chemotherapy on QoL has attracted considerable attention so it was surprising in the context of this section of the book that the authors chose to focus so much on the sarcoma stu-

dies. With the increasing investment of the pharmaceutical industry in QOL assessment in cancer clinical trials and recognition of difficulties in implementation, it was perhaps regrettable that the authors chose to give so much coverage to the psychology of QoL assessment in this volume. Liang *et al.*'s final chapter (chapter 32) on chronic rheumatic disease is most memorable for the three page table of classification of rheumatic diseases, but it does extend the discussion to consider the evaluation of children and adolescents and offers a useful reference list of addresses for updated information on the measures mentioned.

In conclusion, the redundancy in this volume which was at times trying for the reviewer is less of a

problem in the book's more appropriate use as a resource to be dipped into. The model of bringing together the clinical, economic and pharmaceutical industry perspectives is particularly successful. The contributors are predominantly American and it will be interesting to compare the newly published text (*Quality of Life Assessment - Key Issues in the 1990's*) edited by Walker and Rosser in which very similar topics are discussed by European authors. Spilker's book remains a useful anthology to have on one's shelf.

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