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Introduction

Summary

Quality of life (QoL) is a complex concept with multiple dimensions. This book will assume a wide definition for this concept. It will describe the design, assessment, analysis and interpretation of single- and multi-item, subjective measurement scales. These measurement scales all have the common feature of using a standardized approach to assessing a person's perception of their own health by using numerical scoring systems, and may include one or several dimensions of QoL. This chapter will provide a brief history of QoL assessment; describe the different types of QoL assessment tools available and give reasons why it is important to measure QoL.

1.1 What is quality of life?

Quality of life (QoL) is a complex concept with multiple aspects. These aspects (usually referred to as domains or dimensions) can include: cognitive functioning; emotional functioning; psychological well-being; general health; physical functioning; physical symptoms and toxicity; role functioning; sexual functioning; social well-being and functioning; and spiritual/existential issues (see Figure 1.1). This book will assume a wide definition for this concept. It will describe the design, assessment, analysis and interpretation of single- and multi-item, subjective measurement scales. This broad definition will include scales or instruments that ask general questions, such as 'In general, how would you rate your health now?', and more specific questions on particular symptoms and side effects, such as 'During the past week have you felt nauseated?'. These measurement scales all have the common feature of using a standardized approach to assessing a person's perception of their own health by using numerical scoring systems, and may include one or several dimensions of QoL.

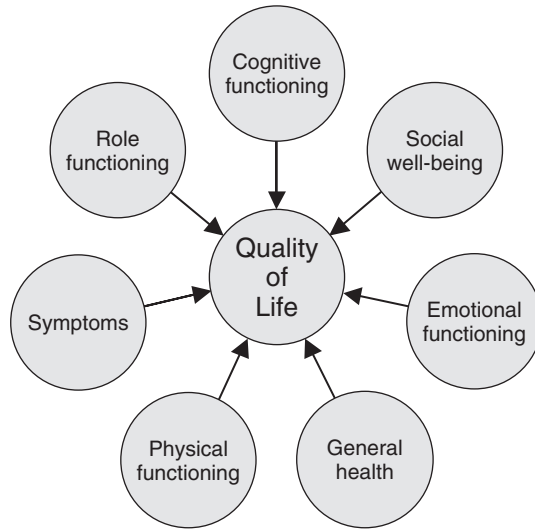


Figure 1.1 Examples of QoL domains.

1.2 Terminology

Researchers have used a variety of names to describe QoL measurement scales. Some prefer to use the term *health-related quality of life* (HRQoL or HRQL), to stress that we are only concerned with health aspects. Others have used the terms *health status* and *self-reported health*. The United States Food and Drug Administration (FDA) has adopted the term *patient-reported outcome* (PRO) in its guidance to the pharmaceutical industry for supporting labelling claims for medical product development (FDA, 2006). However, not all people who complete such outcomes are ill and patients, and hence PRO could legitimately stand for *person-reported outcome*. Mostly, we shall assume that the QoL instrument or outcome is self-reported, by the person whose experience we are interested in, but it could be completed by another person or proxy. The term *health outcome assessment* has been put forward as an alternative which avoids specifying the respondent. This book will follow convention and use the now well-established term *quality of life*.

1.3 History

The World Health Organisation (WHO, 1948) declared health to be ‘A state of complete physical and mental social well-being, and not merely the absence of disease and infirmity’. This definition was one of the first to emphasize other facets of health, such as physical, mental and social, in connection with disease and infirmity.

The Karnofsky Performance Scale (Karnofsky and Burchenal, 1949) was one of the first instruments to undertake a wider assessment of patients’ functional impairment apart from clinical and physiological examination. It involves health-care staff assessing patients, using a simple single-item 11-point scale ranging from 0 for ‘dead’ to 100

Table 1.1 The Karnofsky Performance Scale.

Description	Score
Normal; no complaints; no evidence of disease	100
Able to carry on normal activity; minor signs and symptoms of disease	90
Normal activity with effort; some signs and symptoms of disease	80
Cares for self; unable to carry on normal activity or do work	70
Requires occasional assistance, but is able to care for most personal needs	60
Requires considerable assistance and frequent medical care	50
Disabled; requires special care and assistance	40
Severely disabled; hospitalization indicated although death not imminent	30
Very sick; hospitalization necessary; requires active support treatment	20
Moribund; fatal processes progressing rapidly	10
Dead	0

for 'Normal' (see Table 1.1). It can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients.

This led to the development of the next generation of questionnaires which focused on broader aspects of QoL, such as emotional well-being, social functioning, impact of illness, perceived distress and life satisfaction. These included the Nottingham Health Profile (NHP, Hunt *et al.*, 1980, 1981) and the Sickness Impact Profile (SIP, Deyo *et al.*, 1982). Again, I shall describe the NHP and SIP as QoL scales although their developers neither designed them nor claimed them as QoL scales.

Newer instruments such as the Medical Outcomes Study (MOS) Short Form (SF)-36 (Ware and Sherbourne, 1992) now place more emphasis on the subjective aspects of QoL, such as emotional, role, social and cognitive functioning. The SF-36 is the most commonly used QoL measure in the world today. It contains 36 questions measuring health across eight dimensions: Physical Functioning (PF); Role-Physical (role limitations due to physical health, RP); Social Functioning (SF); Vitality (VT); Bodily Pain (BP); Mental Health (MH); Role-Emotional (role limitations due to emotional problems, RE); and General Health (GH).

Quality of life was introduced by the MEDLINE (Medical Literature Analysis and Retrieval System Online) international literature database of life sciences and biomedical information as a heading in 1975, and accepted as a concept by Index Medicus in 1977. Since then there has been a rapid expansion of interest in the topic, with an exponential increase in the number of citations of QoL in the medical literature (see Figure 1.2).

In 1991, the first edition of a new international, multidisciplinary journal devoted to the rapid communication of original research, theoretical articles and methodological reports related to the field of QoL in all the health sciences was published, entitled *Quality of Life Research*. The February 2004 issue was largely devoted to the publication of abstracts from the first meeting of the International Society for Quality of Life Research (ISOQOL), held in Brussels. ISOQOL's mission is the scientific study of QoL relevant to health and health care. The Society promotes the rigorous investigation of health-related QoL measurement from conceptualization to application and practice. ISOQOL fosters the worldwide exchange of information through scientific publications, international conferences, educational outreach, and collaborative support for QoL initiatives.

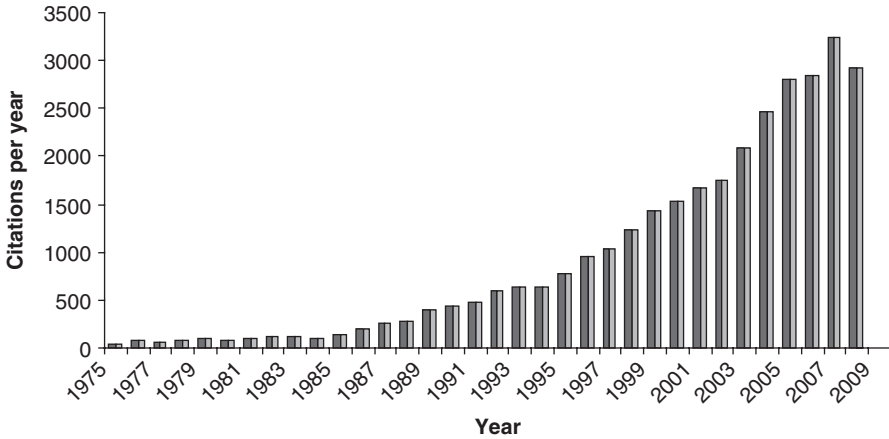


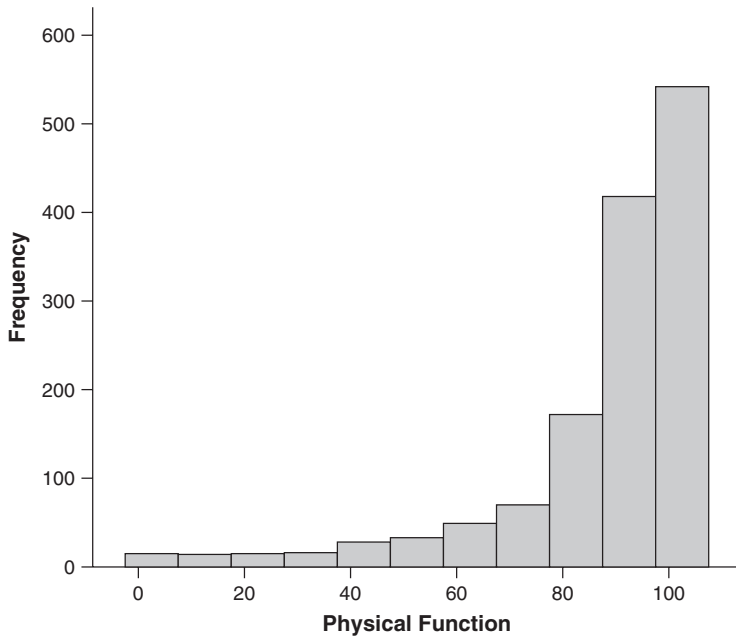
Figure 1.2 MEDLINE database ‘quality of life’ focused subject heading citations, 1975–2008.

1.4 Types of quality of life measures

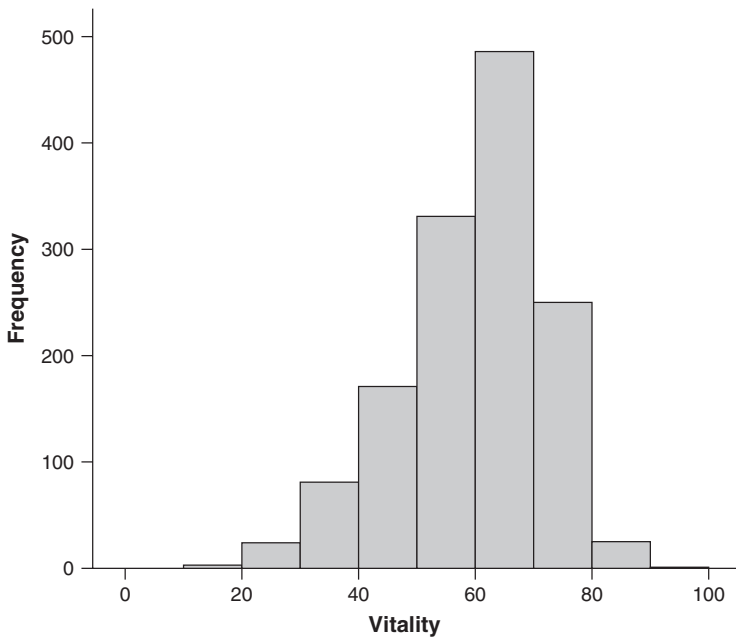
The SF-36 is an example of a QoL instrument that is intended for general use, irrespective of the illness or condition of the patient. Such instruments are often termed *generic* measures and may often be applicable to healthy people too and hence used in population surveys. Figure 1.3 shows the distribution of the eight main dimensions of the SF-36 from a general population survey of United Kingdom residents (Brazier *et al.*, 1992). The SF-36 dimensions are scored on a 0 to 100 (‘good health’) scale. Figure 1.3 shows that the SF-36 outcome, in common with many other QoL scales, generates data with a discrete, bounded and skewed distribution. Figure 1.4 shows how physical functioning in the general population (Walters *et al.*, 2001a) declines rapidly with increasing age.

The SF-36 is also an example of a *profile* QoL measure since it generates eight separate scores for each dimension of health (Figure 1.3). Other generic profile instruments include the SIP and NHP (see Section 1.3). Conversely, some other QoL measures generate a single summary score or *single index*, which combines the different dimensions of health into a single number. An example of a single index QoL outcome is the EuroQol or EQ-5D as it is now named (EuroQol Group, 1990).

Generic instruments are intended to cover a wide range of conditions and have the advantage that the scores from patients with various diseases may be compared against each other and against the general population. For example, Figure 1.5 compares the mean SF-36 dimension scores of a group of patients six months after acute myocardial infarction (AMI) with an age and sex matched general population sample (Lacey and Walters, 2003). The AMI sample has lower QoL on all eight dimensions of the SF-36 than the general population sample. On the other hand, generic instruments may fail to focus on the issues of particular concern to patients with disease, and may often lack the sensitivity to detect differences that arise as a consequence of treatments that are compared in clinical trials. This has led to the development of *condition-* or *disease-specific* questionnaires. Disease-specific QoL measurement scales are comprehensively reviewed by Bowling (2001, 2004). Examples of disease-specific QoL questionnaires include the



(a)



(b)

Figure 1.3 Distribution of the eight SF-36 dimensions from a general population survey ($n = 1372$); a score of 100 indicates ‘good health’ (data from Brazier *et al.*, 1992).

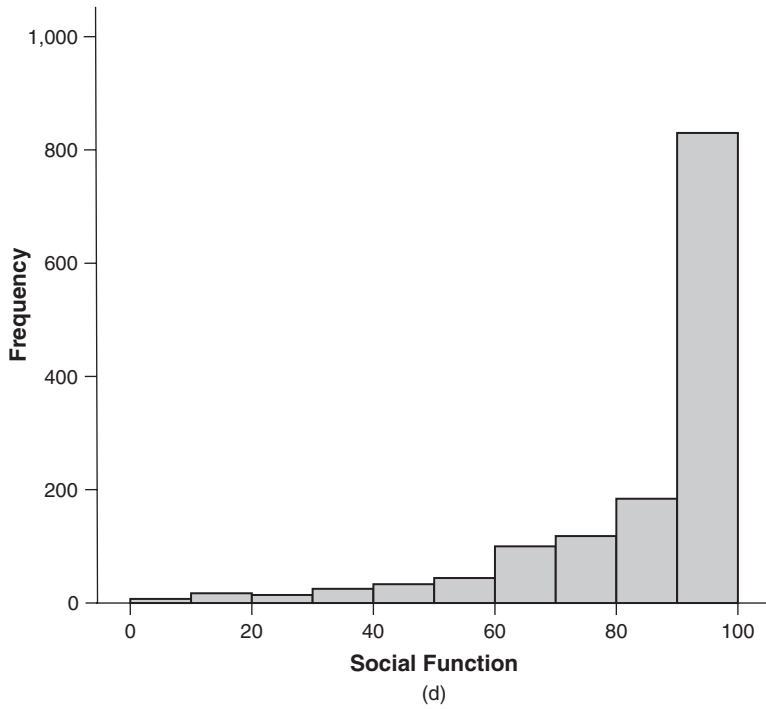
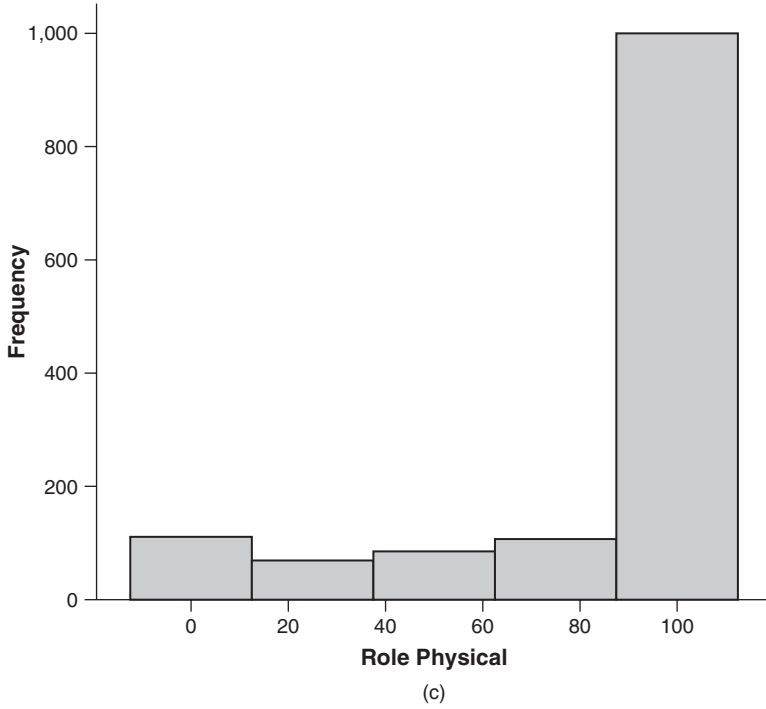


Figure 1.3 (Continued)

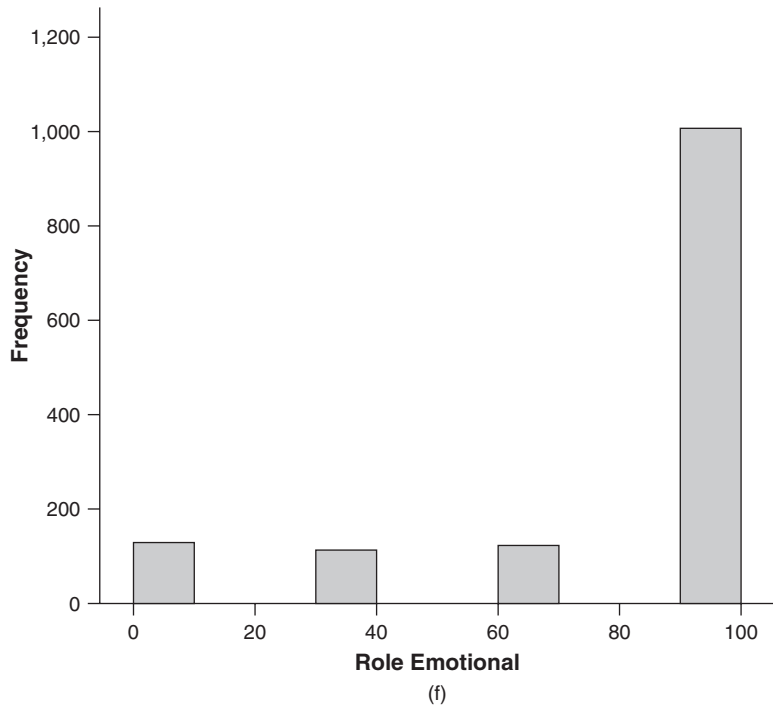
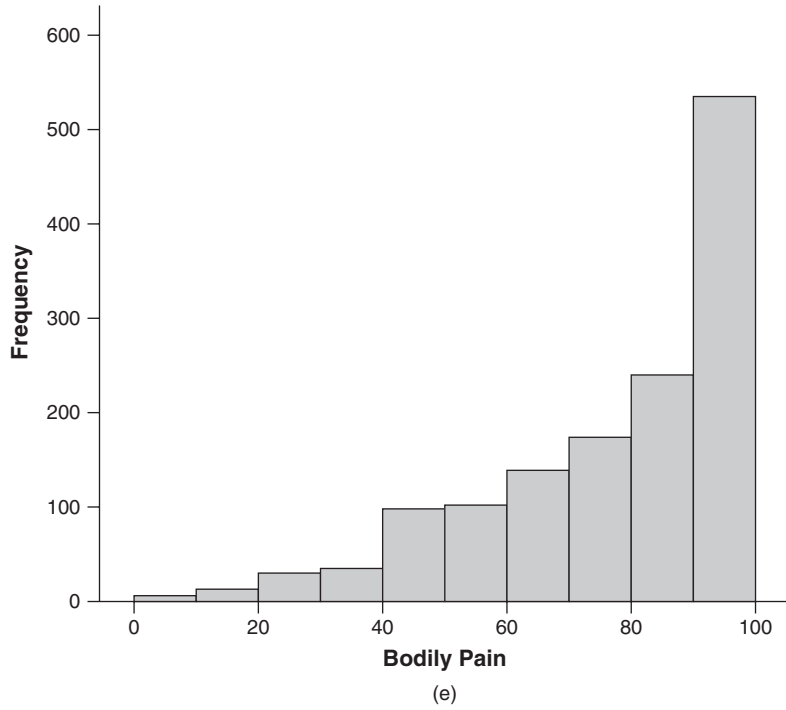


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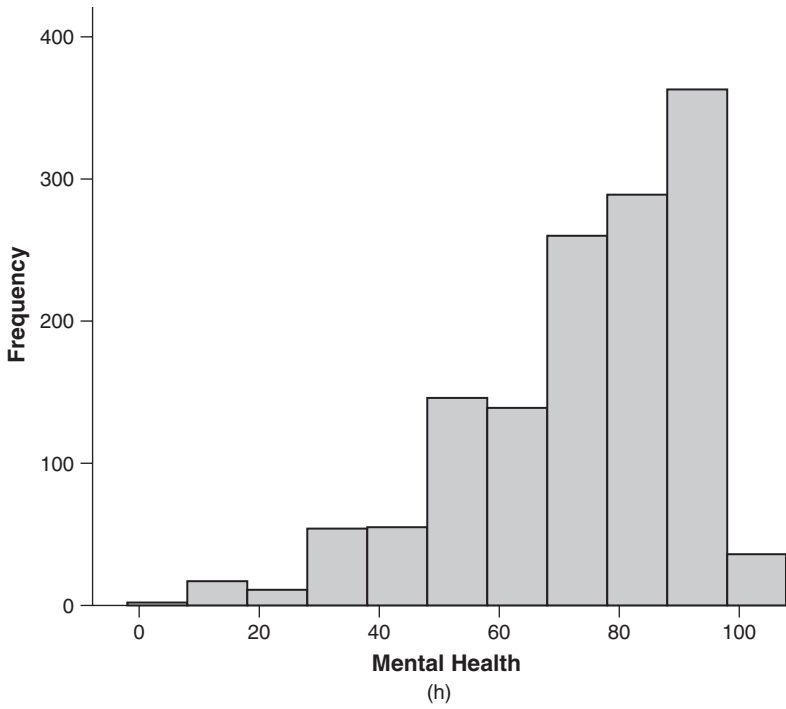
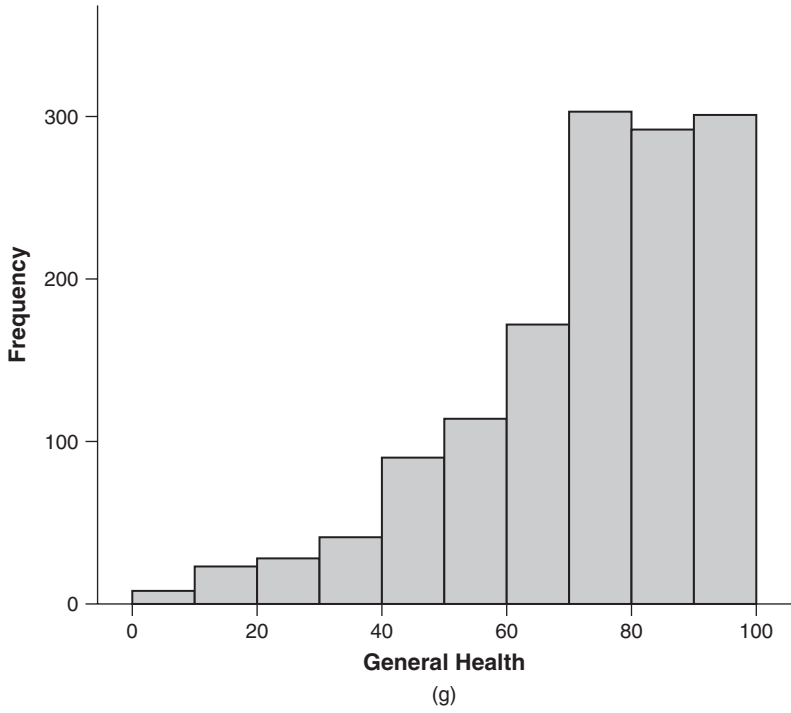


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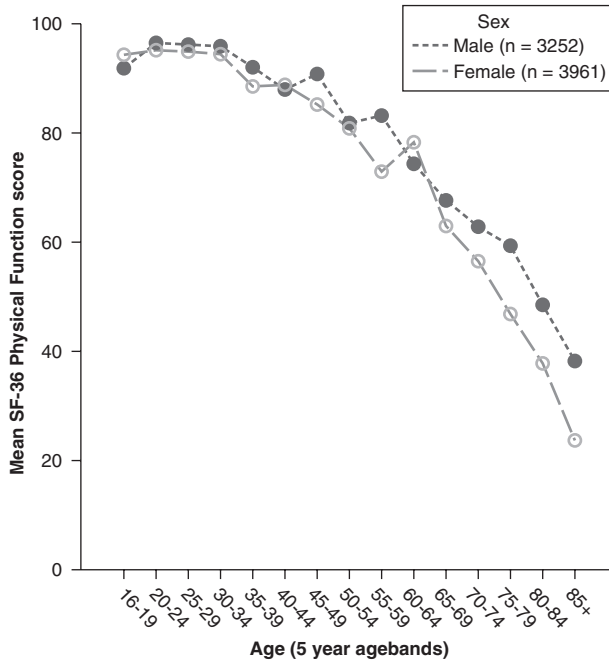


Figure 1.4 Mean SF-36 Physical Functioning age profile by sex (data from Walters *et al.*, 2001a).

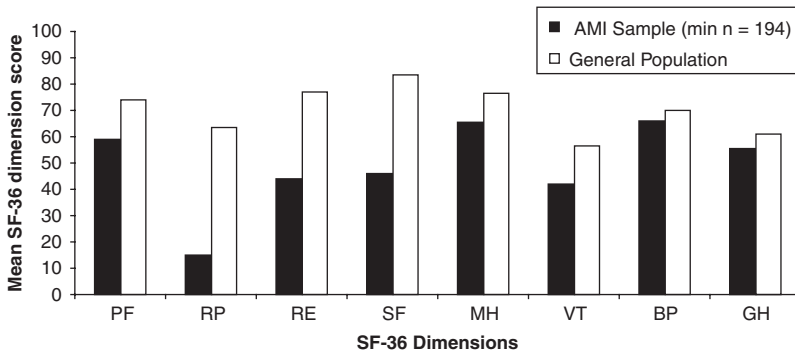


Figure 1.5 Profile of mean SF-36 scores for an acute myocardial infarction sample (six weeks after infarction) compared with an age and sex matched general population sample (data from Lacey and Walters, 2003).

cancer-specific 30-item European Organisation for Research and Treatment of Cancer (EORTC) QLC-30 questionnaire (Aaronson *et al.*, 1993) and the cancer-specific 30-item Rotterdam Symptom Checklist (RSCL, de Haes *et al.*, 1990).

The instruments described above claim to measure general QoL, and usually include at least one question about overall QoL or health. Sometimes investigators may wish to explore particular aspects or concepts in greater depth. There are also instruments

for specific aspects of QoL. These specific aspects may include anxiety and depression, physical functioning, pain and fatigue. Examples of instruments which evaluate specific aspects of QoL are: the Hospital Anxiety and Depression Scale (HADS, Zigmond and Snaith, 1983) and the Beck Depression Inventory (BDI, Beck *et al.*, 1961) instruments for measuring anxiety and depression; the McGill Pain Questionnaire (MPQ, Melzack, 1975) for the measurement of pain; the Multidimensional Fatigue Inventory (MFI, Smets *et al.*, 1995) for assessing fatigue and the Barthel Index (Mahoney and Barthel, 1965) for assessing disability and functioning.

1.5 Why measure quality of life?

There are several reasons why we should measure quality of life in both a research setting and in routine clinical practice. The use of QoL assessment in routine clinical practice may make communication with patients easier and help find out information about the range of problems that affect patients. Medicine and health care have traditionally tended to focus on symptom relief as the main outcome measure. QoL assessment may help improve symptom relief, care or rehabilitation for an individual patient. Using QoL instruments may reveal other issues that are equally or more important to patients than just symptom relief. The patient's self-assessment of their own QoL may differ substantially from the judgement of other health-care staff. Individual patient preferences may also differ from those of other patients. Therefore it is important to measure QoL from the patient's perspective, using a self-completed questionnaire to establish their views and preferences. Cured patients and long-term survivors may have ongoing problems long after their treatment is successfully completed. These ongoing problems may be overlooked, so again it is important to measure QoL long term and to look for late problems of psychosocial adaptation.

QoL assessments may be included in research studies such as randomized controlled trials (RCTs). The main reason is to compare the study treatments with respect to those aspects of QoL that may be affected by the treatment. These treatment comparisons will include both the positive benefits from trials that are expected to improve QoL, and any negative changes, from toxicity and side effects of treatment.

QoL can be a predictor of treatment success, and hence pre-treatment assessment of QoL may have prognostic value. Fayers and Machin (2007) suggest that the direction of the association between QoL scores and treatment outcome is not clear. Do QoL scores reflect an early perception by the patient of the disease progression? Alternatively, does QoL status in some way influence the course of the disease? Whatever the nature of the association, it is important to assess QoL and use it when making medical decisions for individual patients.

QoL assessment can also be used to make decisions on treatments at a population level, rather than an individual patient level. QoL outcomes can be used in economic evaluations alongside clinical trials to assess the clinical and cost-effectiveness of new health technologies.

There is an ongoing thoughtful discussion about the meaning of QoL, and about what should be measured. In the face of this debate, it is still important to measure quality of life as well as clinical and process-based outcomes. This is because 'All of the these [QoL] concepts reflect issues that are of fundamental importance to patients' well-being. They are all worth investigating and quantifying' (Fayers and Machin, 2007).

1.6 Further reading

The two books by Bowling extensively describe the numerous QoL instruments now available (Bowling 2001, 2004). The book by Fayers and Machin (2007) covers all aspects of QoL assessment, analysis and interpretation. Fairclough (2002) goes into more detail about the statistical analysis of QoL data in RCTs with a strong emphasis on imputation methods for missing data and the modelling of longitudinal data. The book edited by Fayers and Hays (2005) covers a variety of topics in its 27 chapters with contributions from 31 authors and provides an overview of QoL assessment, analysis and interpretation.

