We are IntechOpen, the world's leading publisher of Open Access books Built by scientists, for scientists



186,000

200M



Our authors are among the

TOP 1% most cited scientists





WEB OF SCIENCE

Selection of our books indexed in the Book Citation Index in Web of Science™ Core Collection (BKCI)

Interested in publishing with us? Contact book.department@intechopen.com

Numbers displayed above are based on latest data collected. For more information visit www.intechopen.com



Chapter

Modifiers of Health-Related Quality of Life by Biological, Psychological and Social Factors

Jose Antonio Miron Canelo, Maria-Fernanda Lorenzo Gómez, Elena Iglesias De Sena and Luz Celia Fernández Martín

Abstract

Healthcare workers, clinicians and/or researchers require information on the consequences of illness on their patients, as well as on the effects associated with treatments, when making decisions on recommended treatments and for follow-up evaluations of the same. Identifying health indicators which provide necessary and appropriate data for the evaluation of clinical outcomes in terms of Health-Related Quality of Life (HRQoL), as established by the WHO Biopsychosocial Model, and which provide appropriate and pertinent information on physical, mental and social factors in patients, can improve decision-making in relation to a comprehensive and global perspective of clinical outcomes of the various treatments and procedures given to patients. This chapter aims to provide an overview of the various tools for assessing Health-Related Quality of Life, as a growing number of clinicians, researchers and patient groups wish for comprehensive and not merely biological measures of health. This may be explained by the growing number of selfadministered or interview questionnaires which have the aim of measuring changes in health as well as the consequences of the various treatments used mainly on chronicity and chronic health conditions. During recent decades, numerous tools have been developed and applied to the measurement of the effects of Health-Related Quality of Life in patients based on biological or physical aspects, psychological or mental aspects, and social aspects. This chapter will review the most frequently-used tools for the measurement of Health-Related Quality of Life, and recommendations are made for their use in medical care according to psychometric characteristics and quality criteria, as a guide for use in the field of healthcare, in public health, or in outcomes research.

Keywords: Health-Related Quality of Life (HRQoL), health conditions, medical care

1. Introduction

The term "health indicator" refers to a characteristic associated to the health of an individual or a population. In Public Health and in Health Planning, population health indicators are used to show the magnitude of a medical problem, to reflect a change in the health status of a patient or a population over time, to compare and assess differences in health status among patients and populations, and to analyse and evaluate the extent to which treatment goals have been achieved in patients in order to recommend these treatments for use in clinical practice and research [1, 2].

Measurement of health and Health-Related Quality of Life (HRQoL) has acquired great importance in recent decades as a means of measuring clinical outcomes in patients and of monitoring the progress of various treatments along with their physical, psychological and social consequences [3]. Medical practitioners frequently must choose from among diverse tools with the aim of obtaining essential relevant information for decisions on treatment, with analysis and a multidimensional assessment of these treatments on patients.

Meanwhile, countries have health information systems which permit the development of a wide variety of health indicators, and thus allow periodic surveys of their healthcare situation. These indicators provide information on their change over time, which makes it possible to assess trends and geographical distributions. Likewise, the wide availability of these indicators allows comparison with other countries [4, 5].

Selection of indicator sets is commonly done in countries with well-developed health information systems with the aim of providing executive and multidimensional information. Among global health indicators are those whose objective is to assess the perception of improvement in patient functional capacity on a global scale, i.e. assessing subjective patient perception of the physical, mental and social components in a global and comprehensive fashion [6].

The concept of Quality of Life has undergone such rapid development that it is used very frequently and to such an extent that it has become a common expression in both professional settings and the general population. The healthcare sector is not immune to its influence and many professionals rely on it to assess the patient's psychosocial experience and the effects on the disease of medical and surgical interventions and procedures. This term originated in the USA after the end of World War II, during the development of the Welfare State.

The development of HRQoL research is linked to changes during recent decades in the concept of health, whose basis has shifted from a *biomedical* model to a *biopsychosocial* model [7]. This indicator began to be used extensively from the 1980s, especially in connection with the care of chronically ill patients. Patient health and ability to function depends on and is a consequence of several components: physical, mental and social. Therefore patients must be assessed globally and, consequently, the functioning of all three components must be taken into account for a patient to progress as a person and a social individual.

In this context, HRQoL estimates and measures living conditions of patients which are linked to health conditions and/or disease, and has become a fundamental *dependent or response variable* when assessing success of therapeutic or surgical aims in the medical field. In other words, the HRQoL indicator is currently a valuable tool for understanding circumstances linked to disease and medical care.

The first model or framework which was established to measure Quality of Care was described and proposed by *A. Donabedian* [8]. This author proposed a frame-work, now classic, which evaluates three components. Firstly, *structure*, the stable attributes required for care, i.e. the available resources: human, material, technological, financial, etc. This component has been used to accredit hospitals and health centres for teacher training, and to classify hospitals. Teaching posts which are made available for training resident interns are allotted based on this element of quality of care. Secondly, the model must assess and analyse the *process*, the actions taken with the available resources; i.e. the use healthcare providers make of what they have in their clinics, clinical services, medico-surgical services, etc. Thirdly,

Quality of Care*	Structure	Process	Outcome
Focus	What we have	What we do	What we get
Measures/Indicators	Resources	Actions	Health Status HRQoL Wellbeing
*Framework from Avedis Donab	edian.		

Table 1.

Classical model of quality of care.

the model considers *outcome*, i.e. the results in terms of improved health, lifestyle, quality of life and wellbeing (**Table 1**).

The **overall aim** of this chapter is to present the tools for measuring Health-Related Quality of Life (HRQoL) which allow a global, subjective evaluation of patients in connection to the various medical and or surgical procedures which they undergo. These tools should also provide the ability to follow up on the effects and consequences on patients of these procedures from a multidimensional perspective. The information obtained from these indicators enables professional decisionmaking based on relevant, personal and holistic information about patients. The goal of this chapter is also eminently practical: without entering into theoretical considerations, it will perform a methodological review of these tools to facilitate decision-making when choosing generic and/or specific surveys.

2. Methodology

In the field of health, HRQoL measurements are widely used, to the extent that specialist journals exist while non-specialist journals have also, in recent years, published editorials and articles on the subject. Available information on tools for the measurement of HRQoL has been subjected to a review process according to the following criteria: 1. - Adaptation to the objective. 2.-Psychometric criteria of *valid-ity, reliability* and *discriminative power or sensitivity to change*. 3.- Practical utility for health workers, teachers and researchers in various settings and population groups, such as the general population or vulnerable groups (e.g. chronic patients, individuals with disabilities and dependent or frail persons). The measurement tools included in this chapter were chosen according to whether the questionnaires contain items which evaluate physical, psychological and social factors according to the biopsychosocial health model, which was proposed in the 1970s and adapted by the WHO [7] as a means of evaluating HRQoL and wellbeing in patients and across population groups [9–14]. And these have been selected based on metrical quality criteria of previously selected instruments such as:

2.1 Validity

In the measurement of HRQoL, no single method for assessing the validity of measuring instruments exists, as it is an indirect assessment through indicator systems. In other words, there is no single way for a tool to measure what it is intended to measure through *content validity* based on the analysis of the concept to be measured and with a definition of the dimensions covered such that the indicators represent the dimensions of health status to be analysed and evaluated. *Construct validity*, on the other hand, is the relationship between the variable to be measured and the concept indicator being measured, i.e. health [15–19].

2.2 Reliability

The reliability of an instrument is given by its stability or consistency in observations when the process of measurement is repeated under equal or similar conditions. Several types of reliability may be derived from this definition: *test–retest* (stability of the tool if measurement conditions and concept are unchanged), *inter-observer* (if measurement is carried out by multiple observers and the concordance index, kappa, is between 0.8 and 1 [20]), and *internal consistency* (stability of scores among the various elements of the measuring tool) [21].

2.3 Discriminatory power or sensitivity to change

This property requires that small clinical variations due to a treatment or procedure are reflected in the scores given by patients. Evaluating this property is essential in instruments whose sole purpose is assessment. When a measuring tool is used to categorise patients with differing degrees of severity or disability, discriminatory power is vital. A recent study analysed and assessed the Nottingham Health Profile (NHP), the Short Form-36 (SF-36) survey, the Psychological General Well-Being Index (PGWB) and a single-item 0 to 100 Self-Rated Health Scale, evaluating psychometric properties such as internal consistency, construct validity and discriminatory power. The authors conclude that there is high concordance among the three HRQoL tools (PGWB, SF-36 and NHP) in all aspects but the social, and that these tools may identify the presence of self-assessed poor health. The quick, simple Self-Rated Health Scale was strongly correlated with the more time-consuming PGWB, SF-36 and NHP [21]. Reviews have also been published on tools for assessing the properties of instruments measuring quality of life [22].

2.4 Internal consistency

In questionnaires developed to measure different dimensions separately, as it happens when HRQoL is measured, each dimension's internal consistency must be evaluated using Cronbach's alpha. Its values range between 0 and 1 and indicate the degree of agreement between two quantitative variables, similar to the correlation coefficient.

2.5 Strength of recommendation

Following the above psychometric criteria and a qualitative SWOT analysis we identify those tools which meet the criteria of consistency, validity, and discriminative power and which have more strengths than weaknesses and, therefore, represent an opportunity for improving patient HRQoL. While the aim is to provide a quick, eminently practical guide for use in research on health and quality of life for instructors, health workers and researchers, tools must be adapted to socioclinical context and to specific patients.

In summary, generic measures of quality of life are proposed, contrasted against previous studies and other tools with clinical utility in highly prevalent diseases due to their importance and significance in both the general population and in vulnerable groups (such as elderly individuals with morbidity and multiple pathologies, and disabled and/or dependent individuals).

All these tools seek to convert Evidence-Based Medicine (EBM) into Results-Based Medicine (RBM), taking into account biological, physical, mental, emotional and social components in order to improve patient HRQoL and wellbeing. This evolution from EBM to RBM is very important for chronic patients, elderly individuals, and individuals with disabilities, because those components which provide satisfaction in life are improved and thus improve quality of life and wellbeing.

3. Generic HRQoL tools

3.1 SF-36 survey

One of the best-known and most widely used tools for the measurement of HRQoL internationally is the **SF-36 Survey** [23, 24]. This was developed in the US in the 1990s for use in analysis and assessment of clinical outcomes, based on questionnaires which included a variety of concepts related to health.

This tool consists of 36 questions, 35 of which assess health through eight dimensions covering two areas, Functional Status and Emotional Wellbeing. The functional area is represented by the following dimensions: Physical Function (10 items), Social Function (2 items), Role Limitations due to physical problems (4 items), Role Limitations due to emotional problems (3 items). Wellbeing includes the following dimensions: Mental Health (5 items), Vitality (4 items), Pain (2 items). Finally, overall assessment of health includes the dimension Perception of General Health (5 items) and Change in Health Status over time (1 item). Two versions exist: standard, with a 4-week recall period, and acute, with a 1-week recall period. The 36th question covers perceived changes in health in the year prior to the interview.

The SF-36 survey has good validity, reliability and sensitivity to change, giving this tool a Grade A recommendation, i.e. the survey meets sufficient quality criteria. Experts and practitioners who have employed the survey quote numerous reasons for its use, such as ease of use and interpretation, multidimensional assessment, comparability, and use in vulnerable groups [11–13]. Furthermore, the Short-Form survey has several versions according to number of items (36, 12, 8 or 6), enabling it to be generalised and used in multiple contexts and with diverse aims [25–27]. SF-12 was the most used for assessment of clinical outcomes. These diverse versions show good psychometric properties across different patients, population groups and countries. Therefore SF-36 is shown as an effective and reliable tool for the measurement of clinical outcomes in patients with various conditions and across various population groups such as persons with intellectual disabilities [11, 13]. It has been validated in numerous countries and therefore allows comparisons among patients with diverse health conditions, diseases and medical treatments, as well as comparison with a general reference population. Table 2 shows the number of items for each component assessed by the survey. These items register both positive and negative changes in health (Table 2).

In a review of the survey's measuring ability, reliability, validity and responsiveness to instrument change, conducted on 17 chosen articles which assessed the psychometric characteristics of the questionnaire, the reliability of SF-36 scales was greater than the suggested standard (Cronbach's alpha) of 0.7 in 96% of evaluations. The pooled evaluations obtained by meta-analysis were higher than 0.7 in all cases. SF-36 showed good differentiation among groups of varying severity, moderate correlation with clinical indicators, and high correlation with other HRQoL instruments. In addition, the survey scores predict mortality. Therefore, SF-36 and its derivatives are an appropriate tool for use in medical research, as well as in clinical practice; in some countries attempts were made to add the survey to medical records, though this has been less successful [28].

Consequently, the SF-36 survey is a complete instrument which allows the assessment of generic HRQoL or health status in patients by analysing and

Health-Related Quality of Life - Measurement Tools, Predictors and Modifiers

Aspects	Number of items
Physical Functioning	10
Role Limitations: Physical Problems	4
Pain	2
General Health Perceptions	5
Change in Health over Time	1
Vitality	4
Social Functioning	2
Mental Health	5
Role Limitations: Emotional Problems	3

Table 2.

Number of items for each component assessed by the survey.

evaluating various aspects of the patients, and its clinical use is recommended in order to assess the outcomes of treatment or care based on the opinion of the patients, as a reliable, valid tool with sensitivity to change.

Above all, its use is recommended when cure and/or prognosis rates of two treatments are equal, but differences may be seen in the vital and social implications of each treatment (such as chemotherapy with profound side effects, in cases of cancer) or when limitations occur in the patient's life and wellbeing. It may also be used to assess patient satisfaction with the service provided and to assess reintegration to normal life in cases of disabling diseases and conditions or in persons with disabilities [11, 13]. In addition, the survey may be self-administered by patients or be given by an interviewer. According to experts [29], this tool has a Grade A recommendation for its psychometric criteria, for its generalisability for comparisons, and for its recent use in various cohorts such as the elderly and persons with Alzheimer's disease [11–13, 30–32], and in very diverse conditions and circumstances [33–40]. It can therefore be used to assess HRQoL of patients in general and of vulnerable population groups, alone or in combination with other tools. In summary, the SF-36 is a reproducible, short, valid and versatile survey which has even been proposed for use in economic measures of health [41].

3.2 Nottingham health profile

The Nottingham Health Profile was developed in the UK in the late 1970s with the aim of measuring the subjective perception of the impact of health problems. The authors state that it is appropriate for use in assessing medical and/or social interventions, in pre-post or quasi-experimental designs, as a measure of comparisons among cohorts, as a survey tool on selected populations, for long-term follow-up in patients with chronic disease, as a complement to medical history, and for clinical research in selected patient cohorts. In summary, experts state that it is most suitable for patients with significantly impaired health status, because the survey has the *weakness* of lacking items that track positive health [29].

It is a generic tool for measuring the *degree of physical, psychological and social suffering* associated with medical, social and emotional problems that affect the lives of patients.

The survey consists of two parts. The first has 38 questions with 6 dimensions: Energy (3 items), Pain (8 items), Physical Mobility (8 items), Emotional Reactions

(9 items), Sleep (5 items) and Social Isolation (5 items). These items aim to represent various states of health and record Yes/No responses from the patient. The second part consists of 7 questions on health-related limitations to 7 functional activities of daily living: paid employment, household chores, social life, family life, sex life, hobbies and interests, and free or leisure time. The score ranges from 0 to 100 depending on whether a patient's responses are all negative (0) or all positive (100) [42–44]. Six different scores are obtained for each of the dimensions, giving an estimated observation of the patient's perception of their state of health which may be used without staging of the items, simply by taking the number of positive responses divided by the number of items in that dimension and multiplied by 100 to obtain a range of results from 1 to 100 with the same interpretation as globally. The authors recommend the use of scores by dimension, rather than global scores. A short or reduced version exists, with 22 items. It may be self-administered (preferable) or with an interviewer or interviewers. It has been used in patients with coronary disease, lung cancer, undergoing addiction treatment with methadone, and fibromyalgia [45–48]. It is Grade A recommendation for its psychometric criteria, its generalisability for use in comparisons, and for utility in patient followup and in diverse conditions and patient cohorts.

3.3 Sickness impact profile (SIP)

The Sickness Impact Profile (SIP) was developed in the United States with the aim of providing a valid and sensitive measure of perceived health status in order to correctly appraise clinical outcomes during evaluation, planning and programming of health policies. It was designed for the assessment and measurement of dysfunction from in types and degrees of severity of patients and their conditions, although it is specifically designed for patients with moderate or severe deficiencies and dysfunctions [29]. The overall objective of the SIP is the measurement of *dysfunction* caused by disease in critical patients [49] and the assessment of quality of life in patients in need of surgical intervention for urinary diversions [50], defining "dysfunction" as an alteration in the manner of approaching and performing any given activity, with total cessation of the same or with total replacement by a novel activity. In other words, it is a useful tool for the evaluation of disability in the field of Occupational Health, which can improve the objectivity of the committees that assess disability and functional impairment. SIP also evaluates capability in activities of daily living such as resting, eating, household management, recreation, walking, personal hygiene and grooming, work, social integration, state of mind, emotional behaviour and ability to communicate [29].

The SIP is based on the patient's perception of their own illness and not on the professional and scientific concept of that illness. This instrument is based around changes in behaviour and activities of daily living (ADLs) as a result of negative effects of diseases and their consequences, on a simple generic HRQoL scale composed of 136 questions grouped into 12 categories. Of these twelve categories, seven can be grouped into two, Physical or Psychosocial, and five are independent. The physical dimension consists of mobility, ambulation, and body care and movement; the psychosocial dimension has four categories: social relationships, intellectual activity, emotional activity and communication. The five independent categories are sleep and rest, eating, hobbies and entertainment, work, and household tasks.

In this tool the patient must mark only the questions which describe their *circumstances and state of health* at the present moment, and those which are related and/or associated with the disease and its consequences. The result ranges from 0 to 100, where 0 is absence of dysfunction and 100 is maximum dysfunction. It is

obtained by summing the scalar values of items marked by patients divided by the sum of scalar values of all the SIP items and multiplying by 100. It may be self-administered, which is preferable, or given by an interviewer. It is Grade A for its psychometric criteria [29, 51], for its generalisability for comparisons, and for utility in assessments of patient perception of their own health status and the consequences of various diseases such as incontinence, chronic pain and periodontal disease [52–55].

4. HRQoL indicators for prevalent diseases and functional disability

Measurement tools for health and HRQoL in the field of disease have developed considerably and are generally associated with the most prevalent problems present in the population, and therefore in those with most patients. Among these the following can be highlighted:

4.1 Quality of life profile for the chronically ill (PECVEC)

This standardised tool of measurement was developed in 1996 to assess somatic, emotional and social components as well as functioning and well-being in clinical practice [29, 56]. Therefore it may be used in diverse risk groups and when assessing therapeutic measures and analysing the progression of chronicity. It is composed of 40 questions with a Likert-type response scale with 5 scores, from nothing to a great deal. It is a multidimensional assessment involving the following aspects: Physical Capacity (8 items), Psychological Functioning (8 items), Positive Mood (5 items), Negative Mood (8 items), Social Functioning (6 items) and Social Welfare (5 items). Range of scores is 0 to 4 in all items and the highest score corresponds to the highest quality of life in the patient, with the same weight given to physical and psychological aspects and differentiating between social functioning and social well-being. It has been used successfully in epidemiological studies in the general population and in patients with various chronic diseases such as hypertension, DM, rheumatic disease and acute myocardial infarction. It can be selfadministered (preferable) or by an interviewer or interviewers in patients with difficulties, such as persons with visual or intellectual disabilities. It is Grade A for its psychometric criteria, generalisability for comparisons, and utility in assessments of patient perception of their own health status and the consequences of diseases and circumstances on patient quality of life.

4.2 EUROQOL-5D

EQ-5D is a measure of self-perceived health which originated with the desire of integrating the five dimensions considered most relevant to HRQoL: mobility, self-care, habitual activates, pain/discomfort, and anxiety/depression [57]. It is a generic, standardised, self-administered questionnaire, easy to answer and with low cognitive and intellectual load. EQ-5D is widely used around the world, and is available in more than 170 languages, including several versions in Spanish after a rigorous translation process [58, 59]. It is available in multiple formats: paper and electronic. According to the author, EQ-5D's potential in Spain, not merely as a measure of health but also as a basis for economic assessment, would increase if it were systematically incorporated into clinical information [60, 61] and primary care, and were validated for patients with constipation [62]. This can only occur if

healthcare professionals consider that patient-submitted information on HRQoL outcomes is relevant to the management of their clinical work. EuroQol was developed with the aim of making a generic instrument for measuring HRQoL which could be used in applied, clinical and public health research, and which allowed comparisons among countries, but which was also capable of detecting and quanti-fying changes in health status and quality of life. The test was designed to obtain and provide descriptive information on quality of life based on various dimensions, a global value and a value indicating patient preference for a certain desired state of health. It produces a profile of social values which together with years of life create a measure of the outcomes of medical interventions: quality-adjusted life years (QALY) [63].

EuroQol was developed simultaneously in five European countries: England, the Netherlands, Norway, Sweden and Denmark. The content was obtained from a review of the dimensions of the SIP and the Nottingham Health Profile, based on the experience of the researchers who participated in the project. The tool consist of three parts. The first is devoted to description of health status according to 5 dimensions (mobility, personal care, daily activities, pain/discomfort, and anxiety/ depression). These dimensions are rated 1 to 3, 1 No problems, 2 Some problems, and 3 Many problems. In the second part of the test, the patient scores their state of health on a millimetre scale analogous to a 20 mm thermometer (EVA) whose extremes go from 0 (Worst State) to 100 (Best State). This EVA score can be used as a quantitative indicator of state of health. The third part is designed to obtain individual scores of preference for states designed in the descriptive part, with 14 possible states scored from 1 to 3, and in which the patient is also asked where they would place the status "death". The tool is designed to be self-administered (preferable) or through an interviewer or interviewers in patients with difficulties such as persons with visual or intellectual disabilities. It is Grade A for its psychometric criteria, for generalisability which allows studies in diverse diseases and clinical settings, and for utility of the index value in cost-effectiveness studies and especially in the allocation of clinical and care resources [29]. This questionnaire is available at http://www.euroqol.org.

4.3 Duke activity status index (DASI)

This tool was designed to analyse and assess functional capacity in cardiovascular patients based on the patient's ability to perform activities of daily living (ADLs). A version adapted to gravely hospitalised patients was also developed, based on the SUPPORT [29] study, and more recently its use was recommended as a predictor of postoperative morbidity and mortality by assessing tolerance to exercise and thus improving the planning and outcome of surgery [64]. The original questionnaire consisted of 12 items which collect information on the possibilities of performing activities of daily living (ADLs) such as personal care, mobility, household tasks and sexual functioning in the last two weeks; the reduced version does not include sexual functioning. Scores for each item range from 3 (activity performed without difficulty), 2 (activity performed with difficulty) and 1 (activity not performed for reasons of health). If a surveyed patient does not perform the activity for reasons other than health, this question is given the same score as the previous item, as it is assumed that the patient had at least the same difficulty in performing the activity. Each item has a value ranging between 1 and 2.5, such that the score ranges from 11.5 (minimum capacity) to 33 (maximum capacity). The test is designed to be selfadministered (preferable because this eliminates bias) or through an interviewer or interviewers in patients with difficulties such as persons with visual or intellectual

disabilities [13]. It is Grade A for its psychometric criteria of validity, reliability and sensitivity, and permits studies on cardiovascular diseases and conditions, which are among the most prevalent and primary causes of death in developed countries. Additionally, it is predictive in patients with cardiovascular disease.

4.4 General health questionnaire (GHQ)

The aim in developing this measuring tool was the detection of patients suffering from non-psychotic psychiatric disorders. It was validated for patients who requested primary care services from General Practitioners in the UK, to aid these practitioners in detecting psychiatric cases, and was later applied to epidemiological studies in the general population [29]. The questionnaire is based on the multidimensional model of the Biopsychosocial Health Model [7] and specifically for mental disorders. The author wished to distinguish between minor mental conditions and greater disorders which lead to loss of normality in connection with daily living. The tool consists of 140 items and a short 60-item form; further short forms were later developed, of which the 28-item version is the most frequently used. This last is composed of four subscales of 7 items which assess somatic symptoms of psychological origin, anxiety, difficulties in performing daily activities, and subjective perception of depression. The score for these items is 0 in responses better or equal to normal and 1 in responses worse or much worse than normal. The test is designed to be self-administered (preferable because this eliminate bias) and can be completed in under 5 minutes.

It is Grade A for its psychometric criteria of validity, reliability and sensitivity, and the 28-question version has become widely used due to the short time to administer, ease of scoring and good acceptance. Its main weakness is that it is not designed to screen for psychiatric conditions and for minor non-psychotic psychological conditions [29].

4.5 Psychological general well-being index

This survey was developed in the USA for use in community epidemiological studies as an indicator to reveal subjective feelings of well-being or psychological discomfort, i.e. for studies in the general population. The questionnaire consists of 18 items which cover 6 dimensions. The first 14 items have Likert-type answers, with six categories representing degrees of intensity or frequency which may range from 1 to 6 or from 6 to 1 depending on type of item; the remaining four items are scored on a visual analogue scale. The assessed dimensions are: anxiety, depression, positive mood, vitality, self-control and overall health. A global assessment of severe discomfort can be obtained with the lowest score, and of positive well-being with the highest. Scores can also be obtained for each dimension. A 22-item version of the tool exists which was developed by Dupay [65] for use in cardiovascular disease, and whose score ranges from 22 (patients with severe discomfort) to 132 (patients with positive well-being), which has been translated and adapted into Spanish by experts on methodology and HRQoL measurement tools [66]. It is designed to be self-administered (preferable because this eliminates bias). It is Grade A for its psychometric criteria of validity, reliability and sensitivity to change. Its main weakness is the establishing of cut-off points when differentiating between degrees of well-being: positive, negative, and severe discomfort [29].

To summarise and facilitate the analytical analysis and decision-making when choosing an instrument, these are presented in the following **Table 3**.

Instrument	Type of measure	Psychometric Indicators [*]	Characteristics of the more widespread versions	Utility Applicability	Recommendation
SF36	GenericHRQoL	Good	36 items/12th version 8 dimensions	QualityofLife	I/SA/R
Nottingham Health Profile	GenericHRQoL	Good	38 items 6 dimensions	Measurement of physical/ mental and social Suffering	I/SA
Sickness Impact Profile (SIP)	GenericHRQoL	Good	136 items/12th version 12 categories	Diseases repercussions	SA
EuroQol-5D	GenericHRQoL	Good	[3] parts, 8 dimensions, and Visual Scale	Mobility, Personalcare, DailyActivities Malaise, Anxiety Health condition	I/SA
Quality of Life Profile for Chronically Ill patients (PLC)	ChronicIllnesses	Good	40 items 6 dimensions	<i>MultidimensionalQualityofLife</i> Based on the concept by the WHO	I/SA
Duke Activity Status Index (DASI)	PredictorHRQoL	Good	12 items/10th version	<i>FunctionalCapacity</i> Activities of Daily Living	SA/R
General Health Questionnaire (GHQ-28)	MentalHealth	Good	28 items	<i>MentalHealth</i> Psychological Distress	SA/R
Psychological General Well-Being Index (PGWBI)	Psychological well – being	Good	22 items 6 dimensions	<i>Well – being∧Malaise</i> Psychological	SA

 Table 3.

 Summary of the characteristics of the selected HRQoL instruments.

5. Conclusions

For many experts, the best indicators of the effectiveness of health services are *indicators of Health-Related Quality of Life (HRQoL), wellbeing and citizen satisfaction*. These indicators all measure global outcomes in patients and in the population, since *quality of life and well-being* have multidimensional values and account for the perspective of the patient undergoing the clinical and/or surgical interventions, procedures and services which are recommended and prescribed by practitioners, with informed consent, such as treatment and/or functional recovery and rehabilitation.

The **generic surveys** recommended for the assessment of HRQoL as an indicator are those which grant a comprehensive perspective on patients based on the Biopsychosocial Model of Health, placing patients in the main role of the outcome.

Of these surveys, the most widely used at the international level is SF-36 due to quality criteria and because, **it is used as a reference instrument and because** and it allows more comparisons, giving greater consistency to outcomes obtained at different healthcare and social/health centres and across different countries. Alternative questionnaires exist which may be used based on patients and their health and social circumstances.

Alternative questionnaires are available such as the Nottingham Health Profile (NHP) that is better when measuring health impact in populations, or the SIP when one wants to know the perception of illness that patients refer, the main drawback being it has 136 items, thus not recommended in elderly patients. Specific questionnaires can be used based on patient characteristics. If these are chronic, the Quality of Life Profile for Chronically Ill patients (PLC) is a good option. Based on the objectives, if functional capacity is to be assessed, The *Duke* Activity Status *Index (DASI)* is valid, reliable, and sensitive. It is also predictive in patients with cardiovascular alterations, which was its first use. If you want to estimate psychological or mental well-being, the Psychological General Well-Being Index (PGWBI) is appropriate.

On the other hand, all of these questionnaires can be self-administered. Still, patient's cognitive characteristics must be taken into account, basically that they can read and understand the questions correctly so that answers are reliable.

The **goal** of using these questionnaires when assessing HRQoL is the conversion of evidence into effective results which increase patient quality of life and wellbeing, as health is a fundamental resource for life, and this requires applied or clinical research and a public health system for the improvement of quality of care, HRQoL, and wellbeing.

IntechOpen

Author details

Jose Antonio Miron Canelo^{1*}, Maria-Fernanda Lorenzo Gómez^{2,3}, Elena Iglesias De Sena¹ and Luz Celia Fernández Martín^{4,5}

1 Faculty of Medicine, Preventive Medicine and Public Health, University of Salamanca, Spain

- 2 Faculty of Medicine, Department of Surgery, University of Salamanca, Spain
- 3 Urology Department, Hospital Clínico Universitario de Salamanca, Spain
- 4 Faculty of Psychology, University of Salamanca, Spain
- 5 Psychiatry Service, Hospital Clínico Universitario de Salamanca, Spain

*Address all correspondence to: miroxx@usal.es

IntechOpen

© 2021 The Author(s). Licensee IntechOpen. This chapter is distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/3.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

References

[1] Feinstein AR. Clinimetrics. New Haven: Yale University Press, 1987.

[2] Mirón Canelo JA, Alonso Sardón M. Medidas de frecuencia, asociación e impacto. Rev Medicina y Seguridad en el Trabajo 2008; 54: 93-102.

[3] Allison PJ, Locker D, Feine JS. Quality of life: a dynamic construct. Social Science and Medicine 1997; 45: 221-230.

[4] AbouZahr C, Boerma T. Los sistemas de información sanitaria, pilares de la salud pública. Boletín de la Organización Mundial de la Salud, nº 83. 2005.

[5] Galán M. Sistemas de información de Salud Pública. En: Manual de Salud electrónica para directivos de servicios y sistemas de salud. 2011: 253-271.

[6] Herdman MJ. Reflexiones sobre la medición de la calidad de vida relacionada con la Salud en España. Gac Sanit 2005; 19: 91-92.

[7] Engel G. The Need for a New Medical Model: a Challenge for Biomedicine. Science. 1977;196: 129-136.

[8] Donabedian A. Guide Amenican Care Administration. Medical Care Appaisal-Quality and Utilization. New York, EEUU. American Public Health Association. 1969.

[9] Arahna De Macedo L, Mirón Canelo JA. Alonso Sardón M, Del Pino Montes J, Sáenz González MC. Calidad de vida relacionada con la Salud en pacientes con osteoporosis. Rev de Santé Publica de Brasil 2006; 40: 298-303.

[10] Lucas Carrasco R. Calidad de vida y demencia. Med Clin 2007;128:70-75. Doi: 10.1016/S0025-7753(07)72488-0.

[11] Mirón Canelo JA, Alonso Sardón M, Serrano López de las Hazas A, De Godos N. Sáenz González MC. Health Related Quality of Life (HRQL) in people with intellectual disability Pan Am J Public Health 2008; 24(5): 336-344.

[12] Santa Cruz Ruiz S, Mirón Canelo JA, Del Cañizo A, Santa Cruz Ruiz P. Quality of personal and social life in patients with CI. Int J Pediatric Otorhinolaryngology 2011; 75 (supl 1): 81.

[13] Alonso Sardón M, Iglesias de Sena H, Fernández Martín Luz-Celia, Mirón Canelo JA. Do health and social support and personal autonomy have an influence on the health-related quality of life of individuals with intellectual disability?. BMC Health Services Research 2019; 23;19(1):63.

[14] Flores-Fraile, Lorenzo-Gómez MF,
Mirón-Canelo José-A y Otros. Impacto de la Calidad de Vida del tratamiento de Cáncer de Próstata organoconfinado.
Actas Urológicas Españolas 2020; 44(9): 630-636.

[15] Nunnally JC. Psychometric Theory. New York. McGraw-Hill; 1978.

[16] Guyatt GH, "Should Subjects See Their Previous Responses". Journal Chronic Dis 1985; 38: 1003-1007.

[17] Streiner D, Norman GR. Health Measurement Scales. A practical Guide to Their Development and Use. Oxford: Osford University Press; 1995.

[18] Fletcher RH, Fletcher SW, Wagner EH. Clinical Epidemiology: The essentials. Baltimore: Williams & Williams,; 1996.

[19] Sánchez R, Gómez C. Conceptos Básicos sobre validación de escalas["]. Rev Col Psiquiatria 1998; 2: 121-130.

[20] Lantz CA, Nebenzahl E. Behavior and interpretation of the Kappa statistic: resolution of the two paradoxes. J Clin Epidemiol 1996; 49: 431-434.

[21] Krantz E, Wide U, Trimpou P, Bryman I, Landin-Wilhelmsen K. Comparison between different instruments for measuring healthrelated quality of life in a population sample, the WHO MONICA Project, Gothenburg, Sweden: an observational, cross-sectional study. BMJ Open. 2019 Apr 20;9(4):e024454. doi: 10.1136/ bmjopen-2018-024454.

[22] Lorente S, Vives J, Viladrich C, Losilla JM. Herramientas para evaluar las propiedades de medición de los instrumentos de calidad de vida: un protocolo de meta-revisión. *BMJ Open*. 2018; 8 (7): e022829. Publicado el 23 de julio de 2018. doi: 10.1136.

[23] Alonso J, Prieto L, Antó JM. La versión española del SF 36 Health
Survey (Cuestionario de Salud SF 36): un instrumento para la medida de los resultados clínicos. Med Clín (Barc)
1995; 104: 771-776.

[24] Vilagut G, Ferrer M, Rajmil L et al. El cuestionario de Salud SF 36 español: una década de experiencia y nuevos desarrollos. Gac sanit 2005; 19 (2): 135-150.

[25] Fernández García R, Sánchez
Sánchez LC, López Rodríguez MM,
Sánchez Granados G. Efectos de un programa de ejercicio físico y relajación en el medio acuático en pacientes con espondiloartritis: ensayo clínico aleatorizado. Med Clin 2015;145:
380-384. doi: 10.1016/j.medcli.2014.
10.015

[26] Schmidt S, Vilagut G, Garin O, Cunillera O, Tresserras R, Brugulat P, Mompart A, Medina A, Ferrer M, Alonso J. Normas de referencia para el Cuestionario de Salud SF-12 versión 2 basadas en población general de Cataluña. Med Clin 2012;139: 613-25. Doi: 10.1016/j.medcli.2011.
10.024

[27] Iraurgi Castillo J. Uso del índice de utilidad SF-6D en programas de

mantenimiento con metadona. Med Clin 2008;131:437. doi: 10.1157/13126220.

[28] Rebollo P, Morís J, Ortega T, Valdés C, Ortega F. Estimación de un índice de utilidad mediante el uso de la versión española del Cuestionario de Salud SF-36: validez del índice SF-6D frente al EQ-5D. Med Clin 2007;128: 536-537. Doi: 10.1157/13101163

[29] Badia X, Salamamero M, Alonso J.
La medida de la Salud. Guía de escalas de medición en español.¹ 3ª ed.
Fundación Lilly. Barcelona, 2002.

[30] Gomez Pavon. Calidad de vida relacionada con la salud. La punta del iceberg del complejo abordaje de los ancianos muy mayores. Med Clin 2010; 135: 162-164. doi:10.1016/j. medcli.2009.11.025

[31] Amador-Marín B, Guerra-Martín MD. Effectiveness of nonpharmacological interventions in the quality of life of caregivers of Alzheimer. Gac Sanit. 2017 Mar-Apr;31 (2):154-160. Spanish. doi: 10.1016/j. gaceta.2016.09.006.

[32] Garzón-Maldonado FJ, Gutiérrez-Bedmar M, García-Casares N, Pérez-Errázquin F, Gallardo-Tur A, Martínez-Valle Torres MD. Health-Related quality of life in caregivers of patients with Alzheimer's disease. Neurologia. 2017 Oct;32(8):508-515.. doi: 10.1016/j. nrl.2016.02.023. Epub 2016 Apr 25.

[33] Aguirre-Camacho A, Stepanous J,
Blanco-Donoso LM, Moreno-Jiménez B,
Wilburn J, González-Saiz L,
McKenna SP. Adaptation and Validation of the Cambridge Pulmonary
Hypertension Outcome Review
(CAMPHOR) for Use in Spain. Rev Esp
Cardiol (Engl Ed). 2017 Jun;70(6):
467-473. doi: 10.1016/j.rec.2016.11.007

[34] Azevedo C, Pessalacia JDR, Mata LRFD, Zoboli ELCP, Pereira MDG. Interface between social support, quality of life and depression in users eligible for palliative care. Rev Esc Enferm USP. 2017 Aug 28;51:e03245. doi: 10.1590/ S1980-220X2016038003245. PMID: 28902325.

[35] García-León FJ, García-Estepa R, Romero-Tabares A, Gómez-Millán
Borrachina J. Treatment of advanced laryngeal cancer and quality of life.
Systematic review. Acta
Otorrinolaringol Esp. 2017 Jul-Aug;68
(4):212-219. English, Spanish. doi: 10.1016/j.otorri.2016.11.005.

[36] Enríquez Reyna MC, Vargas Flores MLÁ. Factores personales que afectan la calidad de vida de mujeres con cáncer de mama del noreste de México: Personal factors that affect quality of life of women with breast cancer from the northeast of Mexico. Hisp Health Care Int. 2018 Jun;16(2):70-75. doi: 10.1177/ 1540415318786675.

[37] Flores-Ruvalcaba, María L. Peralta-Pedrero, Andrea De Villafranca-Dugelby, Fermín Jurado-Santa Cruz. Quality of life in adults with keloid scars. Martha A. Morales-Sánchez^{*}, Christian N. Cir Cir 2018;86(4):321-326. doi: 10.24875/CIRU.M18000049.

[38] Muñoz-Lasa S, López de Silanes C, Atín-Arratibel MÁ, Bravo-Llatas C, Pastor-Jimeno S, Máximo-Bocanegra N. Effects of hippotherapy in multiple sclerosis: pilot study on quality of life, spasticity, gait, pelvic floor, depression and fatigue. Med Clin (Barc). 2019 Jan 18;152(2):55-58.. doi: 10.1016/j. medcli.2018.02.015.

[39] Mallolas J, Ahumada A, Ampuero J, Blanco JR, Hidalgo Á, Londoño MC, Molina E, Ruiz S. Quality of life in patients with hepatitis C. Importance of treatment. Gastroenterol Hepatol. 2019 Sep;42 Suppl 1:20-25. doi: 10.1016/ S0210-5705(20)30184-9.

[40] Rørvik HD, Campos AH, Styr K, Ilum L, McKinstry GK, Brandstrup B, Olaison G. Minimal Open Hemorrhoidectomy Versus Transanal Hemorrhoidal Dearterialization: The Effect on Symptoms: An Open-Label Randomized Controlled Trial. Dis *Colon Rectum*. 2020 May;63(5): 655-667. doi: 10.1097/DCR. 000000000001588.

[41] Brazier J, Roberts J, Deveill M. The estimation of preference-based measures of health from the SF 36. Health Econ. 2002; 21:272-292.

[42] Alonso J, Antó JM, Moreno C. Spanish versión of the Nottingham Health Profile: translation and preliminary validity. Am J Public Health 1990; 80:704-708.

[43] Alonso J, Prieto L, Antó JM. The Spanish versión of the Nottingham Health Profile: a reeview of adaptation and instrument caharacteristics. Quality of Life Research 1994; 3:385-393.

[44] Prieto L, Alonso J, Viladrich MC, Antó JM. Scaling the Spanish versión of the Nottingham Health Profile: Evidence of limited value of itemweights. J of Cinical Epidemilology 1996; 49:31-38.

[45] Permanyer Miralda G, Brotons C, Cascant P, Moral I, Alonso J, Soler Soler J. Assessment of quality of life related to health 2 years after coronary surgery. Med Clin (Barc). 1997 Mar 29; 108(12):446-451.

[46] Bonfill X, Montes J, Roqué M, Nogué M, Saigi E, Seguí MA, Blanco R, Arcusa A, Arjol A, Diaz C. Evaluation prospectiva de resultados clínicos en los pacientes clínicos con cáncer de pulmón. Med Clín 2000; 114 (suppl 3): 104-111.

[47] Torrens M, San L, Garrell E, Castillo C, Martínez A, Domingo A. Use of the Nottinghal Health Profile for measurin health status of patients in methadone maintenance treatment. Addiction 1997; 92: 707-716.

[48] Bosch Romero E, Sáenz Moya N, Valls Esteve M, Viñolas Valer S. Study of quality of life of patients with fibromyalgia: impact of a health education programme. Aten Primaria. 2002 Jun 15;30(1):16-21. Spanish. doi: 10.1016/s0212-6567(02)78958-0.

[49] Lipsett PA, Swoboda SM, Campbell KA, Cornwell E 3rd, Dorman T, Pronovost PJ. Sickness Impact Profile Score versus a Modified Short-Form survey for functional outcome assessment: acceptability, reliability, and validity in critically ill patients with prolonged intensive care unit stays. J Trauma. 2000 Oct;49(4): 737-743. doi: 10.1097/00005373-200010000-00024.

[50] Prcic A, Aganovic D,
Hadziosmanovic O. Sickness Impact
Profile (SIP) Score, a Good Alternative
Instrument for Measuring Quality of
Life in Patients with Ileal Urinary
Diversions. Acta Inform Med. 2013;21
(3):160-165. doi: 10.5455/
aim.2013.21.160-165.

[51] Badia X, Alonso J. Validity and reproductibility of the spanish version of the SIP. J of Cinical Epidemiology Assessment 1996; 49:359-365.

[52] De Bruin AF, Diederiks JP, de Witte LP, Stevens FC, Philipsen H. Assessing the responsiveness of a functional status measure: the Sickness Impact Profile versus the SIP68. J Clin Epidemiol. 1997 May;50 (5):529-540. doi: 10.1016/s0895-4356 (97)00047-4.

[53] Espuña Pons M. Incontinencia de orina en la mujer. Med Clin 2003;120: 464-472.

[54] McEntee ML, Vowles KE, McCracken LM. Development of a chronic pain-specific version of the Sickness Impact Profile. Health Psychol. 2016 Mar;35(3):228-237. doi: 10.1037/ hea0000257. [55] Ferreira MC, Dias-Pereira AC, Branco-de-Almeida LS, Martins CC, Paiva SM. Impact of periodontal disease on quality of life: a systematic review. J Periodontal Res. 2017 Aug;52(4): 651-665. doi: 10.1111/jre.12436.

[56] Fernández-López JA, Hernández-Mejía R, Siegrist J. El perfil de calidad de vida para enfermos crónicos (PECVEC): un método para evaluar bienestar y funcionalismo en la práctica clínica [Quality of life profile for the chronically ill (PECVEC): a method to evaluate well-being and functioning in clinical practice]. Aten Primaria. 2001; 28(10):680-689. Spanish. doi: 10.1016/ s0212-6567(01)70484-2.

[57] The EuroQol group. EuroQol: a new facility for the measurement of health related quality of life. Health Policy 1990; 16: 199-208.

[58] Badia X, Montserrat S, Herdman M,Segura A. La versión española delEuroQol: descripción y aplicaciones.Med Clin (Bar) 1999; 112(Supl 1):79-86.

[59] Badia X, Montserrat S, Roset M, Herdman M. Feasibility, validity and test.retest realityof scaling methods for healyh states: The visual analogue scale and the time trade-off. Quality of Life Research 1999; 8(4): 303-310.

[60] Pinto JL, Lopez Lavid C, Badia X, Coma A, Benavides D. Cost effectiveness analysis of highly active antiretroviral therapy in HIV asymtomatic patients. Med Clin (Barc) 2000; 114(Supl 3):62-67.

[61] Herdman M, Badia X, Berra S. El EuroQol -5D: una alternativa sencilla para la medición de la calidad de vida relacionada con la salud en Atención Primaria. Aten Primaria 2001; 28(6): 425-430.

[62] Perona M, Mearin F, Guilera M, Mínguez M, Ortiz V, Montoro M, Serra J, Casanova C, Rey E, Onofre Alarcón, Bujanda L, Lima A, Andreu M, Castro M, López A, Carrillo R, Sempere L, Badia X. Cuestionario específico de calidad de vida para pacientes con estreñimiento: desarrollo y validación del CVE-20. Med Clin 2008; 131: 371-377. doi: 10.1016/ S0025-7753(08)72285-1.

[63] Dolan, P.; Kahneman, D. Interpretation of utility and their implications for the valuation of health. The Economic Journal. 2008;118: 215-234.

[64] Riedel B, Li MH, Lee CHA, Ismail H, Cuthbertson BH, Wijeysundera DN, Ho KM; METS Study Investigators. A simplified (modified) Duke Activity Status Index (M-DASI) to characterise functional capacity: a secondary analysis of the Measurement of Exercise Tolerance before Surgery (METS) study. Br J Anaesth. 2021 Jan; 126(1):181-190. doi: 10.1016/j. bja.2020.06.016.

[65] Dupuy HJ. Self-representations of general psycological well-being of american adults. American Public Health Association Meeting. Los Angeles CA. 1978.

[66] Badia X, Gutierrez F, Wiklund I et al. Vality and reliatbility of the spanish versión of the Generall Well-Being index. Quality Life Research 1996; 5: 101-108.