

## Uses and applications of health-related quality of life measures

### The state of play in Spain

The purpose of this paper is to critically review the health-related quality of life (HRQoL) studies conducted in Spain. An electronic bibliographic search was used to investigate the psychometric properties of the HRQoL studies. The data bases explored were the following: Medline, HealthStar, and IME. A specifically developed index was used the GRAQoL index, aiming at the evaluation of 11 psychometric and non-psychometric properties of the study designs. The values of the GRAQoL index range from 0 to 100. The authors conclude that the level of research in HRQoL index range from 0 to 100. The authors conclude that the level of research in HRQoL in Spain is high with a number of research teams being actively involved in many areas of generic and specific quality of life instruments. Further research in HRQoL would provide interesting results for ment assessment of clinical effectiveness.

#### 1. INTRODUCTION

Traditionally, the evaluation of the health status of patients has centred around the use of objective methods based on clinical observation or intervention, such as biological, physiological or anatomic measures. Increasingly, these types of measures are being complemented by the use of Health Related Quality of Life (HRQoL) instruments, which aim to reflect patients' views of their own health status. HRQoL measurement attempts to capture the psychosocial features of the patients' conditions, symptoms of the disease that may be distressing, and/or (physical) functional status of patients.

HRQoL measurements have the advantage, in comparison to clinical variables, of measuring the burden of illness in terms of quality of life, which often may be a variable more relevant for patients than the objective clinical measures. When measuring treatment outcomes, improvements in function, whether physical, mental or

social, are also likely to be more meaningful to patients (and arguably should be more meaningful to clinicians) than measures such as blood pressure, bone densitometry or forced expiratory volume. Interestingly, many studies have shown very little relationship between the two kinds of health measures.<sup>1,2</sup>

It is important that HRQoL measures however should conform to acceptable standards of reliability, validity and sensitivity to change.<sup>3</sup> When a HRQoL questionnaire is developed as a new measure, or when it is translated to another language, its psychometric properties must be tested in order to ensure that the questionnaire is measuring what it is intended to measure (validity), that the scores are reproducible when the questionnaire is administered under the same circumstances (reproducibility) and that it is sensitive to real changes in health status (responsiveness).

In this paper, the degree to which these properties have been tested in HRQoL measures developed or adapted

M. Roset,<sup>1</sup>  
M. Herdman,<sup>2</sup>  
X. Badia,<sup>3</sup>  
E. Baró<sup>1</sup>

<sup>1</sup>Health Outcomes Research Europe

<sup>2</sup>Agència d'Avaluació de Tecnologia y Recerca Mèdiques

<sup>3</sup>Department of Clinical Epidemiology, Hospital de la Santa Creu y Sant Pau, Barcelona, Spain

Χρήσεις και εφαρμογές των εργαλείων μέτρησης της ποιότητας ζωής στην υγεία. Η υπάρχουσα κατάσταση στην Ισπανία

Περίληψη στο τέλος του άρθρου

#### Key words

Applications to Spain

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for use in Spain is reviewed, together with the ways in which these questionnaires have been used to date.

## 2. THE CURRENT STATE OF VALIDATIONS

In 1999, Badia et al<sup>4</sup> performed a bibliographic search for quality of life measures which had been adapted or developed for use in Spain, and reviewed the extent to which those measures had been validated and applied in Spanish populations. The search was performed in three electronic data bases (Medline, HealthStar and IME), and hand searches were performed of conference abstracts, references in articles located and doctoral theses at the University of Barcelona. No constraints were used as regards the date of publication. For all questionnaires located the investigators responsible for the development or adaptation of the Spanish versions of HRQoL questionnaires were contacted in order to obtain additional information about the validation and adaptation process.

For all the identified questionnaires the process of development, adaptation and validation was evaluated using a specially developed index (the GRAQoL index). The GRAQoL index evaluates 11 psychometric and non-psychometric aspects of the questionnaires (tbl. 1), including the process by which the instrument was ada-

pted in the case of instruments developed outside Spain and translated for use in this country. This is an important aspect of instrument development, in which a fairly rigorous translation process needs to be used,<sup>5</sup> once it has been decided that the instrument is appropriate for use in a given cultural context.<sup>6</sup> Each aspect was rated as not applicable (NA), not performed or not known whether performed (rated as 0), or performed (rated as 2). The global score of the index is obtained by summing the scores assigned to the 11 items, dividing by the maximum score obtained for the applicable items and multiplying by 100. This gives a global score ranging from 0 (no development) to 100 (maximum development).

Table 2 shows the GRAQoL index scores for the 61 questionnaires identified in Spain, classified as generic, specific and other related instruments (functional disability, psychological well-being, social health or pain). The best developed questionnaires are the generic measures with a median index of 77.7 (defined as good development), followed by the specific measures with a median index of 64.5 (defined as acceptable development). The less well developed instruments are those related to HRQoL with a median index of 50 (defined as between poor and acceptable development). The level of development reflects the history of the various kinds of measurements, the first questionnaires developed being the generic instruments, followed by the disease-specific instruments.

Figure 1 shows the number of HRQoL measures developed for use in Spain depending on the area of measurement. More than half (52.5%) are specific questionnaires, 18% are generic questionnaires and 29.5% measure specific aspects related to HRQoL.

## 3. USES AND APPLICATIONS OF HRQoL MEASURES

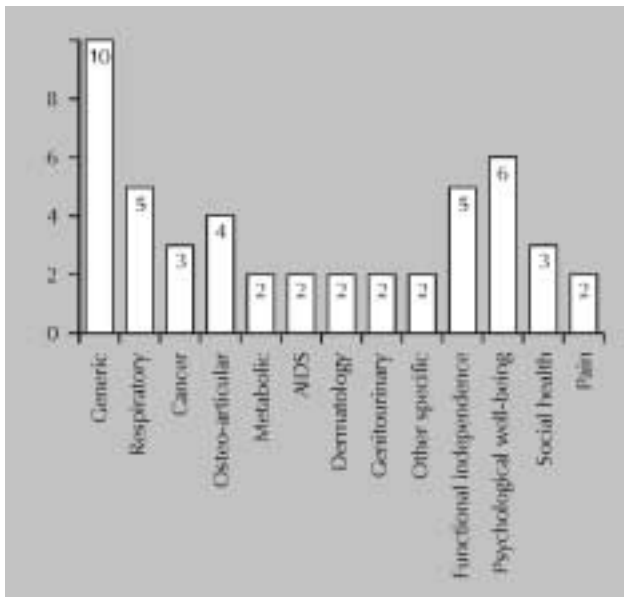
HRQoL measures are applied in several situations, including daily clinical practice, clinical research, epidemiological surveys and economic evaluation of health technology.

**Table 1.** Description of the GRAQoL index.

Translation and back-translation	
Pilot test of the adaptation	
Weights validity/adaptation	
Structural validity	
Convergent validity	
Cut-points adaptation/validity	
Sensitivity in different populations (discriminant validity)	
Internal consistency (reliability)	
Test-retest reliability	
Between observers reliability	
Sensitivity to change	
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GRAQoL score =	$\frac{\text{Some of real scores in applicable items}}{\text{Maximum scores in applicable items}} \times 100$

**Table 2.** Description of GRAQoL index scores in HRQoL existing in Spanish depending on the kind of the questionnaire.

Kind of instrument	n	Min-max	Median	Mean (SD)
Generic measures of HRQoL	11	25–100	77.7	72.9 (26.4)
Specific measures of HRQoL	32	0–100	64.5	62.3 (22.2)
Other measures (functional disability, psychological well-being, social health, pain)	18	11–80	50.0	50.4 (20.6)
Total	61	0–100	62.5	60.7 (23.5)



**Figure 1.** Number of HRQoL measures developed in Spain depending on the kind of measurement.

### 3.1. Using HRQoL measures in clinical practice

In daily practice, HRQoL instruments can be used to analyse needs, to define intervention objectives, to monitor the patients' HRQoL or to improve patient-doctor communication. Although HRQoL instruments are not yet widely used in Spain in this context, to a large extent this is probably because many existing measures are too long to be feasible for use in the clinical setting. Thus, it becomes important to take into account not only the psychometric properties mentioned above, but also the notion of "feasibility", which can be defined in terms of how long it takes to administer a measure and the ease with which it can be administered (i.e. whether it can be self completed without help by the majority of respondents, or whether it requires interviewer administration, etc.).

Identifying the HRQoL measurements with a development level (GRAQoL index) higher than or equal to 70% and limiting the maximum administration time to 15 minutes, only 3 generic measures are identified as potentially applicable in usual Spanish clinical practice: the SF-36,<sup>7,8</sup> the COOP-WONCA<sup>9,10</sup> and the EQ-5D<sup>11,12</sup> with 36, 7 and 6 items respectively. All three questionnaires are self-administered, and none takes over 10 minutes to complete. They are probably also the most frequently used generic questionnaires in clinical practice in Spain. In terms of disease-specific instruments, a number have been produced in short version, but the major-

ity of them have not yet been adapted for use in Spain.<sup>13</sup>

### 3.2. Using HRQoL measures in clinical investigation

In Spain, as in most countries, HRQoL measurement has probably been most widely used in clinical research. Determining the degree to which alternative treatments differ in terms of their impact on HRQoL and assessing the extent to which a given treatment improves HRQoL over time require that instruments be particularly sensitive to between group differences and to changes over time, respectively. Most of the longer instruments used to date have shown acceptable discriminant validity and sensibility to change. It was observed, however that, with regard to the instruments developed or adapted for use in Spain, this was the least widely tested of instrument properties.

When several instruments exist to measure ERQoL in the same pathology or patient group, it becomes necessary to compare instruments so that researchers are aware of which is likely to be the "best" instrument for their particular purposes. Studies carried out recently by Spanish researchers in this line have included comparisons of instruments for use in HIV and AIDS patients,<sup>2</sup> and instruments developed to measure HRQoL in patients with vertebral fractures due to osteoporosis.<sup>14</sup> In both of these studies, it was possible to show differences between instruments in terms of their capacity to detect differences in HRQoL between different patient groups and/or their capacity to detect changes in HRQoL over time.

### 3.3. Using HRQoL measures in epidemiological surveys

HRQoL instruments have been used in at least one large-scale epidemiological survey performed in Spain. In 1996, the EQ-5D was included in the Catalan Health Interview Survey, a cross-sectional study of a random sample of the non-institutionalised general population in Catalonia. The EQ-5D was administered in 12,245 direct interviews. The EQ-5D proved useful in this context precisely because it is a short instrument which is usually completed in three to four minutes. It is also proved to be a highly reliable and valid instrument, which detected differences in HRQoL according to age, sex, educational level and health care region.<sup>15</sup> As in other surveys of this nature, HRQoL was seen to worsen with age, particularly in the dimensions of pain/discomfort and mobility, and women scored consistently worse than men on most of the EQ-5D dimensions.

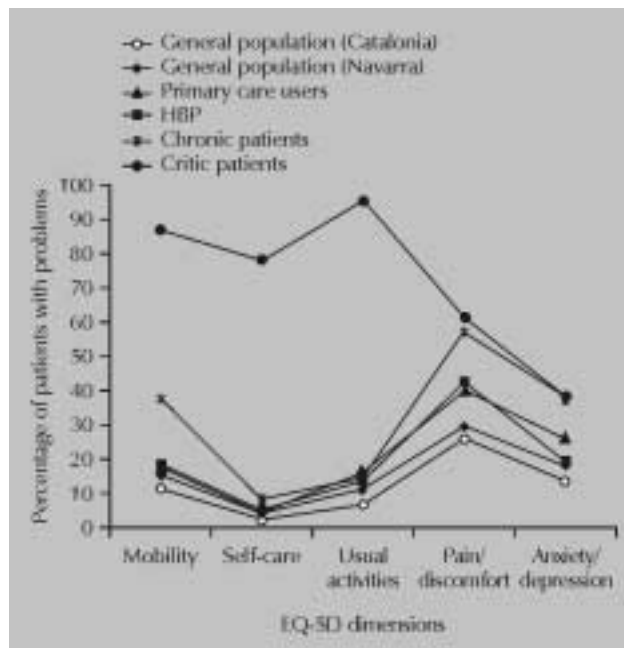
### 3.4. Using HRQoL measures in economic evaluation

Some HRQoL instruments such as the EQ-5D or the Health Utilities Index (HUI)<sup>16</sup> have been designed in order to facilitate their incorporation in the economic analysis of health care. The advantage of these instruments is that they generate standardised health states which facilitate the “valuation” of health states by raters. The EQ-5D for example generated 243 health states which can be valued by raters using econometric techniques such as the Time Trade-Off (TTO) or the Standard Gamble (SG).<sup>17,18</sup> The values obtained in this way can be combined with life expectancy data after a given intervention to generate quality-adjusted life years (QALYs). An alternative to the econometric methods is the Visual Analogue Scale (VAS), which consists of a linear scale divided into intervals with fixed limit points (usually 0 and 100) which represent the worst imaginable health state and perfect health respectively. Individuals then locate a given health state on the VAS to reflect their preference for that state.

In Spain, general population preference values for EQ-5D health states have been obtained using the VAS and the TTO.<sup>19,20</sup> The EQ-5D health states are derived from the descriptive system (valuing 5 dimensions of quality of life in 3 different problem levels), obtaining 243 health states. In both methods the states were rated as hypothetical health states for a sample of general population. A recent comparison of Spanish and UK general population values for EQ-5D health states obtained using a standard TTO methodology showed certainly differences in terms of preferences for health states, with Spanish raters showing a greater aversion to health states with poor mobility and self-care and UK raters showing greater aversion to health states with high levels of pain/discomfort and anxiety/depression.<sup>20</sup> This indicates that care may need to be taken when applying preference values obtained for use for economic evaluation in one country to studies in other countries, as there is no guarantee that the value structures of the different populations will be similar. Research in Spain has also shown that patient and general population preference values tend to differ, at least in the critical care setting.<sup>21</sup>

## 4. INTERPRETING HRQoL OUTCOMES

The traditional clinical variables used in daily clinical practice or health research have been widely analysed in terms of reference scores, so that their interpretation is easy and comprehensible for clinicians and rese-



**Figure 2.** Percentage of individuals from different populations with problems in each of the EQ-5D dimensions.

archers. For example, when a clinician identifies a patient with a systolic blood pressure of 190 mmHg the clinician knows that this patient’s hypertension is poorly controlled. The fact that HRQoL measures are fairly recent developments makes it somewhat more difficult to interpret scores or score changes of these measures. For example, in terms of quality of life, the clinician may ask what does a scores of 56 on the general health dimension of the SF-36 actually mean?

Given the difficulties inherent in interpreting scores on HRQoL measures it has been necessary to develop interpretation methods, one of which is that of developing population standards of reference for each questionnaire.<sup>22,23</sup> Comparing scores obtained from the sample of patients under study with scores obtained from an equivalent sample of the general population, the impact of a given disease on the HRQoL of patients can be identified. In Spain, population standards of reference have been obtained for the SF-36<sup>24</sup> and the ED-5D.<sup>12</sup> Figure 2 shows an example of the application of the EQ-5D reference scores in order to evaluate the impact of different diseases on HRQoL.

## 5. CONCLUSION

Research on HRQoL in Spain is at quite an advanced level with a number of research teams active in various

contexts. The quality of the research performed is generally high, although the level of development of some of the measures used is perhaps not all that could be wished for. HRQoL measures are becoming increasingly widely accepted, and interest among health care pro-

fessionals is high. Future research should probably concentrate on areas in HRQoL research which remain understudied in many countries, particularly the systematic incorporation of such instruments into clinical practice.

## ΠΕΡΙΛΗΨΗ

### Χρήσεις και εφαρμογές των εργαλείων μέτρησης της ποιότητας ζωής στην υγεία. Η υπάρχουσα κατάσταση στην Ισπανία

M. ROSET,<sup>1</sup> M. HERDMAN,<sup>2</sup> X. BADIA,<sup>3</sup> E. BARÓ<sup>1</sup>

<sup>1</sup>Health Outcomes Research Europe, <sup>2</sup>Agència d'Avaluació de Tecnologia y Recerca Mèdiques,

<sup>3</sup>Department of Clinical Epidemiology, Hospital de la Santa Creu y Sant Pau, Barcelona, Spain

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Σκοπός της μελέτης αυτής είναι η κριτική εξέταση των ερευνών που έχουν γίνει στην Ισπανία με θέμα τη μέτρηση της ποιότητας ζωής στην υγεία. Ηλεκτρονικές βάσεις ερευνών έχουν χρησιμοποιηθεί για την αναζήτηση των μελετών που έχουν δημοσιευθεί στον τομέα της ποιότητας ζωής στην υγεία. Οι βάσεις δεδομένων είναι οι Medline, HealthStar και IME. Για τις ανάγκες της έρευνας κρίθηκε σκόπιμο να αναπτυχθεί ένας δείκτης που λαμβάνει τιμές 0 έως 100 και αξιολογεί την ποιότητα των δημοσιευμένων ερευνών με ειδική αναφορά στην ικανοποίηση 11 ψυχομετρικών κριτηρίων. Οι συγγραφείς της μελέτης αυτής συμπεραίνουν ότι το επίπεδο της έρευνας στον τομέα της ποιότητας ζωής στην Ισπανία βρίσκεται σε πολύ καλό επίπεδο. Ένας μεγάλος αριθμός ερευνητών ασχολείται με τη χρήση των εργαλείων μέτρησης της ποιότητας ζωής, τόσο σε γενικές μετρήσεις που αναφέρονται στον πληθυσμό, όσο και σε ειδικές, που έχουν κλινικό χαρακτήρα και αναφέρονται σε ειδικές κατηγορίες ασθενειών. Περαιτέρω έρευνα στον τομέα αυτό θα συμβάλει στην αξιολόγηση της κλινικής αποτελεσματικότητας.

**Λέξεις ευρετηρίου:** Αξιολόγηση, Εφαρμογές στην Ισπανία, Ποιότητα ζωής

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*Corresponding author:*

M. Roset, Health Outcomes Research Europe, C/Plató 6, First Floor, SApt. 08021 Barcelona, Spain  
 e-mail: mroset@hor-europe.com