VALIDATION STUDIES



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# Adaptation of the osteoarthritis-specific quality of life scale (the OAQoL) for use in Germany, Hungary, Italy, Spain and Turkey

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Abstract The Osteoarthritis Quality of Life scale (OAQoL) is specific to individuals with osteoarthritis. The present study describes the adaptation of the OAQoL for use in the following five European languages: German, Hungarian, Italian, Spanish and Turkish. The study involved three stages in each language; translation, cognitive debriefing (face and content validity) and validation. The validation stage assessed internal consistency (Cronbach's alpha), reproducibility (test-retest reliability using Spearman's rank correlations), convergent and divergent validity (correlations with the Health Assessment Questionnaire, The Western Ontario and McMaster Universities Index of osteoarthritis and Nottingham Health Profile) and known group validity. The OAQoL was successfully translated into the target languages with minimal problems. Cognitive debriefing interviewees found the measures easy to complete and identified few problems with content. Internal consistency ranged from 0.94 to 0.97 and test-retest reliability (reproducibility) from 0.87 to 0.98. These values

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indicate that the new language versions produce very low levels of measurement error. Median OAQoL scores were higher for patients reporting a current flare of osteoarthritis in all countries. Scores were also related, as expected, to perceived severity of osteoarthritis. The OAQoL was successfully adapted for use in Germany, Hungary, Italy, Spain and Turkey. The addition of these new language versions will prove valuable to multinational clinical trials and to clinical practice in the respective countries.

# Background

Osteoarthritis (OA) is the most common rheumatic disease producing a high proportion of physical disability world-wide [1]. It is estimated that 9.6% of men and 18.0% of women aged 60 or over have symptomatic OA [2]. Due to an ageing population, the prevalence of OA is predicted to double by 2031 [3].

Most patient-reported outcome (PRO) instruments used in OA studies and clinical practice focus on the impairments and functional limitations caused by the disease [4]. However, while these outcomes are important to both patients and professionals, they do not necessarily have a major impact on quality of life (QoL) [5]. The Osteoarthritis Quality of Life Scale (OAQoL) was designed to provide an overall assessment of the impact of OA and its treatment on individuals' ability to meet their needs [6]. It is a 22-item needs-based measure that provides an unidimensional index of OA-specific QoL. The OAQoL, developed in the UK, has been shown to have very good psychometric qualities and has been validated for use in upper limb, lower limb and combination OA [6]. In order to make the OAQoL more available for use in European clinical studies and health-care settings, the European League Against Rheumatism funded a study designed to translate and validate the measure for use in Germany, Hungary, Italy, Spain and Turkey.

The adaptation of a questionnaire into a new language presents several linguistic and conceptual challenges. Specific nuances and phrases may be well understood by native speakers but may need to be expressed differently in target languages. In order to overcome these challenges, needsbased QoL scales are adapted according to a standardised procedure that uses the dual-panel methodology [7]. This approach involves conducting a bilingual panel (to provide the initial translation into the target language) followed by a lay panel (where items are assessed for comprehension and 'naturalness' of language). The aim of the translation process is to produce items that are understood in the same way in each language. The dual-panel methodology emphasises conceptual over literal equivalence. Where a 'natural' translation for an item is not available, it is necessary to find a phrase that describes an equivalent concept using other words. Wherever possible, items are expressed in common (everyday) language that will appeal to future respondents.

Following translation, it is necessary to show that the new language versions are consistent, reproducible and that they are valid. It cannot be assumed that this will automatically be true, simply because the original version has good qualities.

The aim of this article is to report on the cross-cultural adaptation the OAQoL for use in Germany, Hungary, Italy, Spain and Turkey.

# Methodology

The three adaptation stages were conducted in each country: translation of the questionnaire, cognitive debriefing interviews with OA patients to establish face and content validity in the new cultures and a validation survey. Ethics committee approval was received for each centre included in the study.

## Translation

The dual-panel translation methodology [8] was applied in each country. Both translation panels consisted of five or six local people who worked as a team to decide on the most appropriate wording for instructions, items and response options. Patients were excluded as the panels are designed to produce appropriate translations of items rather than to comment on their suitability. The same group leader attended both panels to ensure that the meaning of items did not change. His/her role was to encourage panel members to reach consensus and to encourage each member to contribute equally.

Bilingual panel members were required to be fluent in English but worked predominantly in the target language. These panels were also attended by one of the original instrument developers whose role was to explain the precise conceptual meaning of the items to panel members. Alternative translations suggested by individual group members were discussed by the group until agreement on the best wording was reached. Where consensus could not be reached, alternative versions of the item were taken forward for consideration by the lay panel.

The lay panels consisted of local people of average or below average educational achievement who only worked in the target language. The purpose of this second panel was to ensure that the final wording of items was appropriate for the average potential future respondent. Group members considered the items in terms of comprehension and acceptability. In particular, they were encouraged to suggest changes in wording that would make the items sound more 'natural' while maintaining their original meaning. Where necessary they were also asked to choose between alternative translations suggested by the bilingual panel.

## Cognitive debriefing interviews

Twenty OA patients were required for the cognitive debriefing interviews in each country. They were required to fulfil the American College of Rheumatology criteria for the diagnosis of knee, hip and/or hand OA [9-11].

Face to face interviews were conducted with these OA patients to test the applicability, comprehension, relevance and comprehensiveness of the translated scales. Interviews were conducted by a trained interviewer. During the interviews, respondents were asked to complete the questionnaire in the presence of an interviewer who noted any obvious difficulties or hesitations over specific items. Respondents were then asked to comment on the instructions, items and response format. In order to assess applicability, respondents were asked about the relevance of the questionnaire items and whether any important aspects of their OA experience had been omitted.

#### Validation survey

Surveys were conducted with approximately 150 OA patients in each country in order to establish the psychometric properties of the new language versions. In Germany, Italy and Spain, postal surveys were conducted. In Hungary and Turkey, patients completed the forms at their outpatient clinic. Patients were recruited from the Rheumatology departments of each individual centre. Again, patients were required to fulfil the American College of Rheumatology criteria for the diagnosis of knee, hip and/or hand OA. Patients with symptomatic, clinically diagnosed foot OA confirmed by X-ray also participated. Exclusion criteria included comorbidity judged by the clinician as likely to affect QoL, presence of failed joint arthroplasty for OA, arthroplasty in the previous 6 months and illiteracy.

The OAQoL consists of 22 dichotomous items with total scores able to range between 0 and 22. High scores indicate poor QoL. The OAQoL was administered on two occasions approximately two weeks apart. Participants were also asked to provide demographic information, to rate their perceived severity of OA and whether they were currently experiencing a flare. They also completed the following scales, in which (as with the OAQoL) high scores indicate worse impairment or functioning:

- The Western Ontario and McMaster Universities Index of Osteoarthritis (WOMAC) 3.0 Likert version [12]. This is a knee and hip OA-specific measure providing pain (score 0–20), stiffness (score 0–8) and functioning limitations on movement (score 0–68) subscales.
- The Health Assessment Questionnaire (HAQ) [13] is a generic disability index assessing functional limitations in activities of daily living: scored 0–3.
- The Nottingham Health Profile (NHP) [14]. This is a generic health status measure consisting of Energy level, Pain, Physical mobility, Sleep, Social isolation and Emotional reaction sections. Each section is scored 0–100. The NHPD [15] is a 24-item unidimensional measure of distress embedded in the NHP.

All assessments were made at both time points.

Non-parametric statistical analyses were used throughout due to the ordinal nature of the measures employed. All statistical tests are two-tailed with a p value of 0.05 indicating statistical significance.

Alpha coefficients were employed to assess internal consistency and Spearman rank correlation coefficients to determine test-retest reliability (reproducibility) and convergent validity. Known group validity was assessed using Mann-Whitney U tests for two groups or Kruskal-Wallis one-way analysis of variance tests for more than two groups. Known group validity is a form of criterion validity that determines whether the new measure distinguishes between scores of members of groups considered likely to differ. The two groups tested were self-perceived severity rating of OA and whether the patient was experiencing a flare-up or not.

# Results

# Translations

Demographic details for the bilingual and lay panels are shown in Table 1. The bilingual panels in each country were able to translate all instructions, response options and items without any major problems. Where difficulties finding the correct wording for items were found, alternative phrases were sent for consideration by the lay panels.

In general, the panels felt that the original English questionnaire was clear and understandable and did not present major translation problems. For the Turkish adaptation, the item I get embarrassed using stairs in public caused some discussion as, in Turkish, the phrase 'using stairs' is uncommon and could easily be misinterpreted by respondents. Thus, the panel decided that 'Toplum içinde merdiven inip çıkarken utanıyorum' (I get embarrassed going up and down stairs in public) was a more appropriate translation for the item.

The word 'isolated' (as in the item I feel very isolated) is not commonly used in Hungary. Bilingual panel members were concerned that patients might confuse it with the word 'lonely.' Despite these concerns, a direct translation (Nagyon elszigeteltnek érzem magma) was sent for consideration by the lay panel.

For the item I worry about being a nuisance to other people, Italian panellists decided to replace 'fastidio' (nuisance) with the word 'peso' (burden), thus making the item more intuitive and easier to understand.

All lay panels were able to choose between alternative translations sent by the bilingual panel. Some additional changes to item wording (that did not alter the meaning) were also made to increase clarity or to make the phrases more colloquial.

## Cognitive debriefing interviews

Interviewee details are provided in Table 1. The samples consisted of OA patients with a good range of age and gender. Interviewees reported the OAQoL to be a simple questionnaire that was easy to complete. Items were found to be clear and relevant. Importantly, no significant aspects of their OA experience that were relevant to QoL had been omitted. Isolated, idiosyncratic difficulties were reported in a few cases:

In Hungary, the word 'physical' was added to the item I'm unable to join in activities with my friends or family, improving its clarity within a Hungarian setting. In Turkey, some patients had difficulty understanding the item I feel like I am missing out on life as they were unclear about what they were missing out on. Consequently, 'opportunities' (firsatları) was added to make the item clearer.

Table 1 Demographics for the translations, cognitive debriefing interviews and validation survey

	Germany	Hungary	Italy	Spain	Turkey
Bilingual translation pa	nel				
n	6	5	5	5	5
Gender					
Male (%)	3 (50.0)	2 (40.0)	2 (40.0)	2 (40.0)	2 (40.0)
Female (%)	3 (50.0)	3 (60.0)	3 (60.0)	3 (60.0)	3 (60.0)
Age (years)					
Mean (range)	48.0 (25.0-69.0)	48.4 (29.0-62.0)	52.6 (22.0-84.0)	49.8 (24.0-80.0)	58.8 (48.0-74.0)
Lay translation panel					
n	5	5	5	5	5
Gender					
Male (%)	2 (40.0)	1 (20.0)	3 (60.0)	2 (40.0)	3 (60.0)
Female (%)	3 (60.0)	4 (80.0)	2 (40.0)	3 (60.0)	2 (40.0)
Age (years)					
Mean (Range)	45.4 (23.0-66.0)	50.0 (40.0-60.0)	47.0 (26.0-61.0)	46.4 (25.0-62.0)	46.0 (40.0-53.0)
Cognitive Debriefing In	nterviews				
n	18	20	20	20	20
Gender					
Male (%)	7 (38.9)	4 (20.0)	5 (25.0)	2 (10.0)	5 (25.0)
Female (%)	11 (61.1)	16 (80.0)	15 (75.0)	18 (90.0)	15 (75.0)
Age (years)					
Mean (SD)	62.1 (12.6)	71.0 (8.9)	67.0 (12.1)	71.0 (12.2)	61.3 (8.4)
Postal validation surve	y				
n	126	134	144	121	156
Gender					
Male (%)	35 (27.8)	34 (25.4)	20 (13.9)	42 (34.7)	32 (20.5)
Female (%)	91 (72.2)	100 (74.6)	124 (86.1)	79 (65.3)	124 (79.5)
Age (years)					
Mean (SD)	64.2 (10.3)	68.9 (9.7)	67.6 (9.0)	68.6 (9.9)	56.0 (10.0)
Duration (years)					
Mean (SD)	9.8 (7.3)	10.1 (5.0)	11.5 (9.2)	16.4 (11.1)	7.2 (6.4)
Perceived severity (%	)				
Mild	19 (15.1)	16 (11.9)	29 (20.1)	18 (14.9)	18 (11.5)
Moderate	57 (45.2)	54 (40.3)	60 (41.7)	46 (38.0)	75 (48.1)
Quite severe	36 (28.6)	52 (38.8)	48 (33.3)	43 (35.5)	42 (26.9)
Very severe	14 (11.1)	12 (9.0)	7 (4.9)	14 (11.6)	21 (13.5)
Reported flare (%)	69 (54.0)	89 (66.4)	107 (74.5)	59 (48.8)	81 (51.9)

# Validation surveys

Details of the samples included in the validation surveys are also shown in Table 1.

Six hundred and eighty-one patients were recruited to the study (ranging from 121 to 156 per country). Of these, 415 (60.9%) were followed up for test-retest purposes. At baseline, the mean age of participants ranged from 56.0 years in Turkey to 68.9 years in Hungary. Approximately three-quarters of the overall sample were female. Most participants rated their disease severity as moderate or quite severe. It can be seen from Table 1 that there were variations in the constitution of the sample in different countries.

#### Questionnaire descriptive scores

OAQoL, HAQ, WOMAC, NHP and NHPD scores are shown in Table 2. Median scores were in the low to mid range of the scales. Some floor effects were found for the OAQoL—especially in Germany and Italy. However, larger floor effects were found on the NHP sections.

Table 2 Questionnaire descriptive scores on the first administration (Median and Inter-quartile range)

Median (IQR)	Germany	Hungary	Italy	Spain	Turkey
OAQoL	6 (1–13)	11 (5–17)	5 (0–11)	6 (1–16)	10.5 (3–17.3)
HAQ	0.88 (0.3–1.4)	1.25 (0.6–1.6)	0.75 (0.3–1.3)	0.56 (0-1.5)	1.0 (0.4–1.5)
WOMAC pain	12 (5–21)	10 (6–14)	5 (3–10)	6 (1–9)	9 (5–13)
WOMAC stiff	6 (2–11)	5 (3–6)	3 (2–4)	1 (0–3)	3 (2–5)
WOMAC function	41 (2–11)	38 (27–52)	20 (10-36)	18 (2–35)	30 (17-42)
NHP					
Energy level	67 (33–67)	33 (33–67)	33 (33–67)	67 (0-83)	67 (33–100)
Pain	12 (0-38)	25 (12-37)	12 (0-25)	12 (0-37)	25 (12-50)
Emotional reactions	33 (11–56)	33 (22-67)	22 (11-44)	33 (0-61)	44 (14–67)
Sleep	20 (0-40)	20 (20-40)	20 (0-40)	20 (0-60)	20 (20-40)
Social isolation	20 (0-40)	20 (20-60)	20 (0-40)	20 (0-40)	20 (20-60)
Physical mobility	38 (25-63)	50 (25-75)	38 (12-63)	38 (0-63)	50 (25-75)
NHPD	6 (3–10)	7 (4–11)	4.5 (1-8)	6 (0.5–11.5)	9 (4–15)

HAO Health Assessment Questionnaire, WOMAC The Western Ontario and McMaster Universities Index of Osteoarthritis, NHP The Nottingham Health Profile; NHPD The Nottingham Health Profile Distress Scale

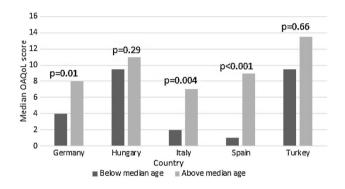


Fig. 1 Median OAQoL scores by age (above and below median)

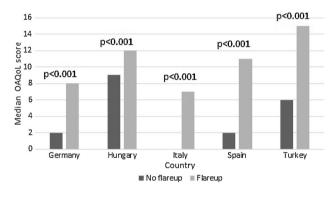


Fig. 2 Median OAQoL scores by perceived flare-up

# Internal consistency and test-retest reliability of the OAQoL adaptations

Cronbach's alpha coefficients ranged from 0.94 to 0.97 indicating adequate inter-relatedness of items. Test-retest reliability coefficients for each language version were also high (0.87-0.98). For the test-retest sample as a whole (n=343), there was no change in median score (6) between administrations. Inter-quartile range at Time 1 was 2-12. At Time 2, it was 1-13. These findings demonstrate that all the adaptations had good reproducibility and that they would produce low levels of measurement error.

#### Questionnaire scores associated with demographic factors

#### Figure 1 shows OAQoL scores associated with age.

Older patients (65 years old and above) scored higher on the OAQoL in Germany, Italy and Spain (p < 0.05). Females scored significantly higher than males in Spain and Turkey. The reasons for these differences are unclear and requires further investigation.

#### Known group validity

Figure 2 shows median OAQoL scores for patients experiencing and not experiencing a flare. The former group scored higher in all countries.

It can be seen from Fig. 3 that OAQoL scores are also clearly related to perceived severity of OA.

#### Convergent and divergent validity

Correlations between OAQoL scores and those on the HAO, WOMAC and NHP sections are shown in Table 3. The pattern of associations was similar across languages. All correlations were relatively high suggesting that all the measures of symptoms and functional limitations influenced quality of life (OAQoL) scores.

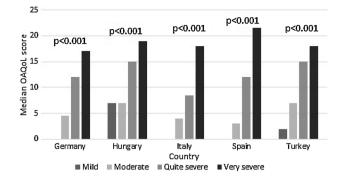


Fig. 3 Median OAQoL scores by perceived OA severity

# Discussion

This paper describes the development and preliminary validation of five new language versions of the OAQoL. All adaptations were shown to be internally consistent, to have good reproducibility and to have evidence of construct validity.

Few difficulties were found in translating the OAQoL into these languages. This finding supports all previous adaptation studies of needs-based measures that employed the dual-panel methodology [see for example; 16–21]. The present adaptation methodology is particularly effective in avoiding translation difficulties and ensuring that the final questionnaire is well understood by patients. This methodology has been shown to produce wording that is preferred by patients [22]. Quality is built into the adaptation process at each stage [7], and this approach emphasises the conceptual rather than literal equivalence of the items to be adapted.

Although the adaptation of the OAQoL was conducted carefully and benefitted from the extensive experience of the research team, cultural differences may well exist that influence how some patients respond to items [23-25]. Such cultural differences are difficult to overcome and it is, as yet, unknown to what degree they may influence the results of international studies where data from multiple countries are combined. However, the results of the cognitive debriefing interviews did not identify any evidence of cultural bias as no items were reported to lack relevance and no consistent reports were made of missing issues in the questionnaire. One advantage of the needs-based model of quality of life is that it does not assess functioning. In contrast, standard patient-reported outcome measures do focus on the symptoms and functional limitations experienced by patients. This can lead to adaptation problems related to culture. For example, when translating 'Walking a block,' should this be changed to 'walking a kilometre' or 'walking half a mile?' Similarly, an item that mentions 'Talking about arthritis problems' will be problematic in certain cultures where it is considered socially unacceptable to discuss one's health problems.

The results suggest that QoL in OA is affected by both age and gender. It was not the purpose of the present study to investigate such findings (as the study was conducted to validate the new language versions developed). However, further evidence is required to determine whether such demographic differences are related to disease severity and/ or whether there is a need to control for age and gender differences in future research studies. Differences were also evident between country samples. The Hungary and Turkish samples had worse quality of life than those from the other countries. These differences could be related to a number of

	Germany $(n=120)$	Hungary $(n=126)$	Italy $(n = 134)$	Spain $(n=121)$	Turkey $(n=150)$
HAQ	0.71	0.78	0.66	0.78	0.70
WOMAC sections					
Pain	0.73	0.61	0.65	0.75	0.60
Stiffness	0.51	0.58	0.70	0.63	0.42
Functioning	0.67	0.70	0.71	0.84	0.67
NHP sections					
Energy level	0.42	0.61	0.57	0.72	0.57
Pain	0.66	0.77	0.52	0.80	0.79
Emotional reactions	0.44	0.65	0.54	0.80	0.67
Sleep	0.42	0.61	0.51	0.80	0.65
Social isolation	0.72	0.71	0.63	0.80	0.70
Physical mobility	0.61	0.72	0.61	0.81	0.69
NHPD	0.71	0.52	0.75	0.84	0.71

All correlations were significant at the 0.01 level (2-tailed)

Table 3Correlations betweenOAQoL scores and those onHAQ, WOMAC and NHPsections

factors including culture, age, duration of illness and differences in health services.

The exclusion criteria for the study matched those for the original development of the OAQoL. These are quite restrictive—as would be the case in a clinical trial. However, for real-life studies, it would be preferable to establish validity in an average population also.

## Conclusions

The adaptation of the OAQoL for use in Germany, Hungary, Italy, Spain and Turkey was successful. All measures were easily adapted and had good psychometric properties. The new adaptations offer greater scope for the investigation of OA in multinational clinical trials involving European countries. They will also be useful in routine clinical practice in these countries.

There is now a large body of high quality needs-based rheumatological measures, that are unidimensional and are capable of co-calibration across different diseases [26–30]. Each measure has been adapted into a wide range of languages. The availability of such an outcomes resource provides a valuable tool for clinicians in everyday practice and for international clinical trials.

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**Conflict of interest** All authors declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual patients included in the study.

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